MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: October 1, 2023 Notification Posted: September 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Daybue (trofinetide)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74653075002020	Daybue	trofinetide oral soln	200 MG/ML	8	Bottles	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Daybue 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of classic/typical Rett syndrome (RTT) **AND** 2. The patient has a disease-causing mutation in the MECP2 gene **AND** 2. If the patient has an FDA approved indication, then ONE of the following**:** A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient's weight is 9 kg or greater **AND** 4. The patient has a baseline (prior to therapy with the requested agent) Rett Syndrome Behavior Questionnaire (RSBQ) and Clinical Global Impression-Improvement (CGI-I) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., improvement in RSBQ or CGI-I) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial: 3 months; Renewal: 12 months

• Program Summary: Filspari (sparsentan)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
56483065000320	Filspari	sparsentan tab	200 MG	30	Tablets	30	DAYS					
56483065000340	Filspari	sparsentan tab	400 MG	30	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 3. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following A. BOTH of the following: 1. The patient's medication history includes at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The presciber has stated that the patient has tried at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB **AND** 2. ONE of the following: A. The ACEI or ARB was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL ACEI or ARB medications **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACEI or ARB, that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL ACEI or ARB that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL ACEI and ARB medications cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. BOTH of the following: 1. The patient has tried and had an inadequate response after a 6 month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The presciber has stated that the patient has tried at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an glucocorticoid **AND** 2. ONE of the following: A. The glucocorticoid was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL glucocorticoids **OR** B. The patient has an intolerance or hypersensitivity to a glucocorticoid **OR** C. The patient has an FDA labeled contraindication to ALL glucocorticoids **OR** D. The prescriber has provided information to support that glucocorticoid therapy is NOT appropriate for the patient **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL glucocorticoids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient will NOT use the requested agent in combination with an ACEI, ARB, endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 8. The patient does NOT have any of the following: A. IgAN secondary to another condition B. Chronic kidney disease C. History of organ transplantation, with exception of corneal transplants D. History of heart failure or previous hospitalization for heart failure or unexplained dyspnea, orthopnea, paroxysmal nocturnal dyspnea, ascites, and/or peripheral edema

Module	Clinical Criteria for Approval
	E. Clinically significant cerebrovascular disease or coronary artery disease within 6 months F. Jaundice, hepatitis, or known hepatobiliary disease or elevations of transaminases (ALT/AST) greater than 2 times upper limit of normal at screening G. History of malignancy other than adequately treated basal cell or squamous cell skin cancer or cervical carcinoma within the past 2 years H. Hematocrit value less than 27% (0.27 V/V) or hemoglobin value less than 9 g/dL (90 g/L) I. Potassium greater than 5.5 mEq/L (5.5 mmol/L) **AND** 9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 9 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio **OR** B. Decrease from baseline (prior to treatment with the requested agent) in proteinuria **AND** 3. The patient will NOT use the requested agent in combination with an angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril), angiotensin II blocker (ARB, e.g., losartan), endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial, 9 months; Renewal, 12 months

• Program Summary: Jesduvroq (daprodustat)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
TBD	Jesduvroq	Daprodustat 1 mg tablets	1 mg	30	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 2 mg tablets	2 mg	30	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 4 mg tablets	4 mg	30	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 6 mg tablets	6 mg	60	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 8 mg tablets	8 mg	90	Tablets	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of chronic kidney disease AND ALL of the following: 1. The patient has been on dialysis for at least 4 months **AND** 2. The patient's hemoglobin was measured in the previous 4 weeks **AND** 3. ONE of the following: A. The patient is currently using an erythropoietin receptor agonist (ESA) (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) AND the patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **OR** B. The patient is NOT currently using an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND** 4. The patient's ferritin was measured in the previous 4 weeks **AND** 5. The patient's ferritin is greater than 100 mcg/L **AND**

Module	Clinical Criteria for Approval
	6. ONE of the following: A. The patient's transferrin saturation (TSAT) is greater than 20% **OR** B. The patient's TSTAT is 20% or lower and is due to recent infection **AND** 7. Other causes of anemia (e.g., pernicious anemia, thalassemia major, sickle cell) have been addressed **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE If Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., increase in hemoglobin) **AND** 3. The patient's hemoglobin was measured within the previous 4 weeks **AND** 4. The patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient will NOT be using the requested agent in combination with an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit

• Program Summary: Skyclarys (omaveloxolone)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74135060000120	Skyclarys	omaveloxolone cap	50 MG	90	Capsules	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Skyclarys 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of Friedreich ataxia (FA, FRDA) with genetic analysis confirming mutation in the frataxin (FXN) gene **AND** 2. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) neurological function (as scored by the modified Friedreich Ataxia Rating Scale [mFARS]) **AND** 3. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., improvement in mFARS score) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months

POLICIES REVISED

• Program Summary: Angiotensin II Receptor Antagonists (ARBs) Renin Inhibitors and Combinations

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36150080002025		Valsartan Oral Soln	4 MG/ML	2400	mLs	30	DAYS				04-29-2022	
36150020100330	Atacand	Candesartan Cilexetil Tab 16 MG	16 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36150020100340	Atacand	Candesartan Cilexetil Tab 32 MG	32 MG	30	Tablets	30	DAYS					
36150020100310	Atacand	Candesartan Cilexetil Tab 4 MG	4 MG	60	Tablets	30	DAYS					
36150020100320	Atacand	Candesartan Cilexetil Tab 8 MG	8 MG	60	Tablets	30	DAYS					
36994002200320	Atacand hct	Candesartan Cilexetil-Hydrochlorothiazide Tab 16-12.5 MG	16-12.5 MG	30	Tablets	30	DAYS					
36994002200340	Atacand hct	Candesartan Cilexetil-Hydrochlorothiazide Tab 32-12.5 MG	32-12.5 MG	30	Tablets	30	DAYS					
36994002200350	Atacand hct	Candesartan Cilexetil-Hydrochlorothiazide Tab 32-25 MG	32-25 MG	30	Tablets	30	DAYS					
36994002300320	Avalide	Irbesartan-Hydrochlorothiazide Tab 150-12.5 MG	150-12.5 MG	30	Tablets	30	DAYS					
36994002300340	Avalide	Irbesartan-Hydrochlorothiazide Tab 300-12.5 MG	300-12.5 MG	30	Tablets	30	DAYS					
36150030000320	Avapro	Irbesartan Tab 150 MG	150 MG	30	Tablets	30	DAYS					
36150030000340	Avapro	Irbesartan Tab 300 MG	300 MG	30	Tablets	30	DAYS					
36150030000310	Avapro	Irbesartan Tab 75 MG	75 MG	30	Tablets	30	DAYS					
36993002050330	Azor	Amlodipine Besylate-Olmesartan Medoxomil Tab 10-20 MG	10-20 MG	30	Tablets	30	DAYS					
36993002050340	Azor	Amlodipine Besylate-Olmesartan Medoxomil Tab 10-40 MG	10-40 MG	30	Tablets	30	DAYS					
36993002050310	Azor	Amlodipine Besylate-Olmesartan	5-20 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Medoxomil Tab 5-20 MG										
36993002050320	Azor	Amlodipine Besylate-Olmesartan Medoxomil Tab 5-40 MG	5-40 MG	30	Tablets	30	DAYS					
36150055200340	Benicar	Olmesartan Medoxomil Tab 20 MG	20 MG	30	Tablets	30	DAYS					
36150055200360	Benicar	Olmesartan Medoxomil Tab 40 MG	40 MG	30	Tablets	30	DAYS					
36150055200320	Benicar	Olmesartan Medoxomil Tab 5 MG	5 MG	60	Tablets	30	DAYS					
36994002500320	Benicar hct	Olmesartan Medoxomil-Hydrochlorothiazide Tab 20-12.5 MG	20-12.5 MG	30	Tablets	30	DAYS					
36994002500340	Benicar hct	Olmesartan Medoxomil-Hydrochlorothiazide Tab 40-12.5 MG	40-12.5 MG	30	Tablets	30	DAYS					
36994002500345	Benicar hct	Olmesartan Medoxomil-Hydrochlorothiazide Tab 40-25 MG	40-25 MG	30	Tablets	30	DAYS					
36150040200340	Cozaar	Losartan Potassium Tab 100 MG	100 MG	30	Tablets	30	DAYS					
36150040200320	Cozaar	Losartan Potassium Tab 25 MG	25 MG	60	Tablets	30	DAYS					
36150040200330	Cozaar	Losartan Potassium Tab 50 MG	50 MG	60	Tablets	30	DAYS					
36150080000330	Diovan	Valsartan Tab 160 MG	160 MG	60	Tablets	30	DAYS					
36150080000340	Diovan	Valsartan Tab 320 MG	320 MG	30	Tablets	30	DAYS					
36150080000310	Diovan	Valsartan Tab 40 MG	40 MG	60	Tablets	30	DAYS					
36150080000320	Diovan	Valsartan Tab 80 MG	80 MG	60	Tablets	30	DAYS					
36994002700340	Diovan hct	Valsartan-Hydrochlorothiaz	160-12.5 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		ide Tab 160-12.5 MG										
36994002700350	Diovan hct	Valsartan-Hydrochlorothiazide Tab 160-25 MG	160-25 MG	30	Tablets	30	DAYS					
36994002700360	Diovan hct	Valsartan-Hydrochlorothiazide Tab 320-12.5 MG	320-12.5 MG	30	Tablets	30	DAYS					
36994002700370	Diovan hct	Valsartan-Hydrochlorothiazide Tab 320-25 MG	320-25 MG	30	Tablets	30	DAYS					
36994002700320	Diovan hct	Valsartan-Hydrochlorothiazide Tab 80-12.5 MG	80-12.5 MG	30	Tablets	30	DAYS					
36150010200320	Edarbi	Azilsartan Medoxomil Tab 40 MG	40 MG	30	Tablets	30	DAYS					
36150010200330	Edarbi	Azilsartan Medoxomil Tab 80 MG	80 MG	30	Tablets	30	DAYS					
36994002100320	Edarbyclor	Azilsartan Medoxomil-Chlorthalidone Tab 40-12.5 MG	40-12.5 MG	30	Tablets	30	DAYS					
36994002100340	Edarbyclor	Azilsartan Medoxomil-Chlorthalidone Tab 40-25 MG	40-25 MG	30	Tablets	30	DAYS					
36993002100330	Exforge	Amlodipine Besylate-Valsartan Tab 10-160 MG	10-160 MG	30	Tablets	30	DAYS					
36993002100340	Exforge	Amlodipine Besylate-Valsartan Tab 10-320 MG	10-320 MG	30	Tablets	30	DAYS					
36993002100310	Exforge	Amlodipine Besylate-Valsartan Tab 5-160 MG	5-160 MG	30	Tablets	30	DAYS					
36993002100320	Exforge	Amlodipine Besylate-Valsartan Tab 5-320 MG	5-320 MG	30	Tablets	30	DAYS					
36994503200330	Exforge hct	Amlodipine-Valsartan-Hydrochlorothiaz	10-160-12.5 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		ide Tab 10-160-12.5 MG										
36994503200335	Exforge hct	Amlodipine-Valsartan-Hydrochlorothiazide Tab 10-160-25 MG	10-160-25 MG	30	Tablets	30	DAYS					
36994503200340	Exforge hct	Amlodipine-Valsartan-Hydrochlorothiazide Tab 10-320-25 MG	10-320-25 MG	30	Tablets	30	DAYS					
36994503200320	Exforge hct	Amlodipine-Valsartan-Hydrochlorothiazide Tab 5-160-12.5 MG	5-160-12.5 MG	30	Tablets	30	DAYS					
36994503200325	Exforge hct	Amlodipine-Valsartan-Hydrochlorothiazide Tab 5-160-25 MG	5-160-25 MG	30	Tablets	30	DAYS					
36994002450325	Hyzaar	Losartan Potassium & Hydrochlorothiazide Tab 100-12.5 MG	100-12.5 MG	30	Tablets	30	DAYS					
36994002450340	Hyzaar	Losartan Potassium & Hydrochlorothiazide Tab 100-25 MG	100-25 MG	30	Tablets	30	DAYS					
36994002450320	Hyzaar	Losartan Potassium & Hydrochlorothiazide Tab 50-12.5 MG	50-12.5 MG	30	Tablets	30	DAYS					
36150070000310	Micardis	Telmisartan Tab 20 MG	20 MG	30	Tablets	30	DAYS					
36150070000320	Micardis	Telmisartan Tab 40 MG	40 MG	30	Tablets	30	DAYS					
36150070000340	Micardis	Telmisartan Tab 80 MG	80 MG	30	Tablets	30	DAYS					
36994002600320	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 40-12.5 MG	40-12.5 MG	30	Tablets	30	DAYS					
36994002600340	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 80-12.5 MG	80-12.5 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36994002600345	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 80-25 MG	80-25 MG	30	Tablets	30	DAYS					
36170010100320	Tekturna	Aliskiren Fumarate Tab 150 MG (Base Equivalent)	150 MG	30	Tablets	30	DAYS					
36170010100340	Tekturna	Aliskiren Fumarate Tab 300 MG (Base Equivalent)	300 MG	30	Tablets	30	DAYS					
36996002150320	Tekturna hct	Aliskiren-Hydrochlorothiazide Tab 150-12.5 MG	150-12.5 MG	30	Tablets	30	DAYS					
36996002150325	Tekturna hct	Aliskiren-Hydrochlorothiazide Tab 150-25 MG	150-25 MG	30	Tablets	30	DAYS					
36996002150340	Tekturna hct	Aliskiren-Hydrochlorothiazide Tab 300-12.5 MG	300-12.5 MG	30	Tablets	30	DAYS					
36996002150345	Tekturna hct	Aliskiren-Hydrochlorothiazide Tab 300-25 MG	300-25 MG	30	Tablets	30	DAYS					
36994503450310	Tribenzor	Olmesartan-Amlodipine-Hydrochlorothiazide Tab 20-5-12.5 MG	20-5-12.5 MG	30	Tablets	30	DAYS					
36994503450340	Tribenzor	Olmesartan-Amlodipine-Hydrochlorothiazide Tab 40-10-12.5 MG	40-10-12.5 MG	30	Tablets	30	DAYS					
36994503450350	Tribenzor	Olmesartan-Amlodipine-Hydrochlorothiazide Tab 40-10-25 MG	40-10-25 MG	30	Tablets	30	DAYS					
36994503450320	Tribenzor	Olmesartan-Amlodipine-Hydrochlorothiazide Tab 40-5-12.5 MG	40-5-12.5 MG	30	Tablets	30	DAYS					
36994503450330	Tribenzor	Olmesartan-Amlodipine-Hydrochlorothiazide Tab 40-5-25 MG	40-5-25 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36993002700330	Twynsta	Telmisartan-Amlodipine Tab 40-10 MG	40-10 MG	30	Tablets	30	DAYS					
36993002700320	Twynsta	Telmisartan-Amlodipine Tab 40-5 MG	40-5 MG	30	Tablets	30	DAYS					
36993002700350	Twynsta	Telmisartan-Amlodipine Tab 80-10 MG	80-10 MG	30	Tablets	30	DAYS					
36993002700340	Twynsta	Telmisartan-Amlodipine Tab 80-5 MG	80-5 MG	30	Tablets	30	DAYS					

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of approval:** 12 months

• Program Summary: Benign Prostatic Hypertrophy (BPH)

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36202040100105		Terazosin HCl Cap 1 MG (Base Equivalent)	1 MG	30	Capsule	30	DAYS					
36202040100120		Terazosin HCl Cap 10 MG (Base Equivalent)	10 MG	60	Capsules	30	DAYS				09-01-2016	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
36202040100110		Terazosin HCl Cap 2 MG (Base Equivalent)	2 MG	30	Capsules	30	DAYS					
36202040100115		Terazosin HCl Cap 5 MG (Base Equivalent)	5 MG	30	Capsules	30	DAYS					
56851020000120	Avodart	Dutasteride Cap 0.5 MG	0.5 MG	30	Tablets	30	DAYS				09-01-0216	
36202005100310	Cardura	Doxazosin Mesylate Tab 1 MG	1 MG	30	Tablets	30	DAYS					
36202005100320	Cardura	Doxazosin Mesylate Tab 2 MG	2 MG	30	Tablets	30	DAYS					
36202005100330	Cardura	Doxazosin Mesylate Tab 4 MG	4 MG	30	Tablets	30	DAYS					
36202005100340	Cardura	Doxazosin Mesylate Tab 8 MG	8 MG	60	Tablets	30	DAYS				09-01-2016	
568520252075	Cardura xl	doxazosin mesylate tab er	4 MG ; 8 MG	30	Tablets	30	DAYS				09-01-2016	
56859902300120	Entadfi	Finasteride-Tadalafil Cap	5-5 MG	30	Capsules	30	DAYS					
56852070100110	Flomax	Tamsulosin HCl Cap 0.4 MG	0.4 MG	60	Capsules	30	DAYS				09-01-2016	
56859902250120	Jalyn	Dutasteride-Tamsulosin HCl Cap 0.5-0.4 MG	0.5-0.4 MG	30	Capsules	30	DAYS				09-01-2016	
56851030000320	Proscar	Finasteride Tab 5 MG	5 MG	30	Tablets	30	DAYS				09-01-2016	
568520600001	Rapaflo	silodosin cap	4 MG ; 8 MG	30	Capsules	30	DAYS				09-01-2016	
56852010107530	Uroxatral	Alfuzosin HCl Tab ER 24HR 10 MG	10 MG	30	Tablets	30	DAYS				09-01-2016	

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Fibrates – *Discontinued*

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

This program will be discontinued, effective 10/1/2023.

• Program Summary: Neurotrophic Keratitis

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86770020202020	Oxervate	Cenegermin-bkbj Ophth Soln 0.002% (20 MCG/ML)	0.002%	56	Vials	56	DAYS					

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of neurotrophic keratitis (NK) **AND** 2. The patient has stage 2 (persistent epithelial defect [PED]) or stage 3 (corneal ulcer) NK **AND** 3. ONE of the following: A. The patient has NOT been previously treated with the requested agent in the affected eye(s) AND ALL of the following: 1. The patient's PED and/or corneal ulcer have been present for at least 2 weeks **AND** 2. ONE of the following: A. The patient's NK has been refractory to at least ONE conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application, botulinum A toxin treatment) **OR** B. The patient has an intolerance or hypersensitivity to at least ONE conventional non-surgical treatment for NK **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL conventional non-surgical treatments for NK **OR** D. The patient's medication history includes at least ONE conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application, botulinum A toxin treatment) AND ONE of the following: 1. The conventional non-surgical treatment was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional non-surgical treatment **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL conventional non-surgical treatments for NK cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient has decreased corneal sensitivity within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant **OR** B. The patient has been previously treated with the requested agent in the affected eye(s) AND BOTH of the following: 1. The patient had complete corneal healing in the previously treated eye(s) **AND** 2. The patient has a recurrence of neurotrophic keratitis (NK) that requires another treatment course **AND** 4. ONE of the following: A. The patient does NOT have ocular surface disease(s) associated with or in conjunction with NK **OR** B. BOTH of the following: 1. The patient has ocular surface disease(s) associated with or in conjunction with NK **AND** 2. The ocular surface disease(s) has been properly treated **AND** 5. The patient will NOT be using the requested agent in combination with a topical ophthalmic NSAID **AND** 6. The patient does NOT have any of the following: A. Active ocular infection or active ocular inflammation not related to NK in the affected eye **OR** B. Severe blepharitis and/or severe Meibomian gland disease in the affected eye **OR** C. History of any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK **OR** D. Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., optometrist, ophthalmologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 8 weeks NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The patient has bilateral NK **AND** B. The requested quantity (dose) does NOT exceed TWICE the program quantity limit **Length of Approval**: 8 weeks

● Program Summary: Ophthalmic Pilocarpine *(formerly known as 'Vuity')*

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86501030102017	Vuity	Pilocarpine HCl Ophth Soln	1.25 %	5	mL	30	DAYS				07-01-2022	

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND BOTH of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: 12 months

● Program Summary: Ophthalmic Prostaglandins

Applies to:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86330015002020		Bimatoprost Ophth Soln 0.03%	0.03 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86330015002010	Lumigan	Bimatoprost Ophth Soln 0.01%	0.01 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300700020	Travatan z	travoprost ophth soln	0.004 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
86330052102020	Vyzulta	Latanoprostene Bunod Ophth Soln 0.024%	0.024 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
86330050002020	Xalatan	Latanoprost Ophth Soln 0.005%	0.005 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
86330050001620	Xelpros	Latanoprost Ophth Emulsion 0.005%	0.005 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300650020	Zioptan	tafluprost preservative free (pf) ophth soln	0.015 MG/ML	30	Containers	30	DAYS		Wastage is significant but cannot be avoided.			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND BOTH of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of approval**: 12 months