MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: July 1, 2023 Notification Posted: June 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Furoscix (furosemide)

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
3720003000F720	Furoscix	Furosemide Subcutaneous Cartridge Kit	80 MG/10ML	8	KITS	180	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of New York Heart Association (NYHA) Class II or Class III chronic heart failure with congestion due to fluid overload **AND** 2. The patient has ONE of the following: A. An estimated creatinine clearance of >30 mL/min **OR** B. An estimated glomerular filtration rate of >20 mL/min/1.73m^2 **AND** 3. The requested agent will NOT be used in emergency situations **AND** 4. BOTH of the following: A. ONE of the following: 1. The patient is currently treated with a loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg for 4 weeks **OR** 2. The patient has an intolerance or hypersensitivity to another loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg **OR** 3. The patient has an FDA labeled contraindication to ALL other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg 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** B. The patient will NOT be using the requested agent in combination with another loop diuretic agent and will be transitioned back to oral diuretic maintenance therapy after discontinuation of requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) 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:** 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	**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:

Module	Clinical Criteria for Approval
	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 **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: Tezspire (tezepelumab-ekko)

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
4460807525D520	Tezspire	tezepelumab-ekko subcutaneous soln auto-inj	210 MG/1.91ML	1	Pen	28	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. 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 severe asthma AND ALL of the following: 1. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**

Module	Clinical Criteria for Approval
	D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND** 2. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 3. ONE of the following: A. The patient is currently being treated for at least 3 months with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with LABA, LTRA, LAMA, or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL LABA, LTRA, LAMA, AND theophylline therapies **AND** 4. ONE of the following: A. If the patient has a diagnosis of allergic type asthma, then ONE of the following: 1. The patient has tried and had an inadequate response to Xolair used for a minimum of 4 months for the treatment of allergic asthma AND ONE of the following: A. The patient has had an inadequate response to Xolair **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Xolair **OR** 2. The patient has an intolerance or hypersensitivity to Xolair **OR** 3. The patient has an FDA labeled contraindication to Xolair **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that Xolair 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 **OR**

Module	Clinical Criteria for Approval
	B. If the patient has a diagnosis of oral corticosteroid dependent type asthma, then ONE of the following: 1. The patient has tried and had an inadequate response to Dupixent used for a minimum of 4 months for the treatment of asthma AND ONE of the following: A. The patient has had an inadequate response to Dupixent **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Dupixent **OR** 2. The patient has an intolerance or hypersensitivity to Dupixent **OR** 3. The patient has an FDA labeled contraindication to Dupixent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that Dupixent 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 **OR** C. If the patient has a diagnosis of eosinophilic type asthma, then ONE of the following: 1. The patient has tried and had an inadequate response to Dupixent AND an IL-5 inhibitor (e.g., Fasenra, Nucala) used for a minimum of 4 months for the treatment of asthma AND ONE of the following: A. The patient has had an inadequate response to Dupixent AND an IL-5 inhibitor (e.g., Fascnra, Nucala) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Dupixent AND an IL-5 inhibitor (e.g., Fascnra, Nucala) **OR** 2. The patient has an intolerance or hypersensitivity to Dupixent AND an IL-5 inhibitor **OR** 3. The patient has an FDA labeled contraindication to Dupixent AND IL-5 inhibitors **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that Dupixent AND an IL-5 inhibitor (e.g., Fasenra, Nucala) 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

Module	Clinical Criteria for Approval
	achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The prescriber has provided information indicating the patient has severe asthma that is not allergic type, eosinophilic type, or oral corticosteroid dependent type **AND** 5. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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. ONE of the following: A. The patient has a diagnosis of severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**

Module	Clinical Criteria for Approval
	D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** B. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent OR C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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
	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:** Initial - 6 months; Renewal - 12 months

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Adbry (tralokinumab-ldrm) Actemra (tocilizumab) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Nucala (mepolizumab) Olumiant (baricitinib) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Zeposia (ozanimod)

POLICIES REVISED

• Program Summary: Antidepressant

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
58300040100310		Bupropion HCl Tab 100 MG	100 MG	120	TABS	30	DAYS					
58300040100305		Bupropion HCl Tab 75 MG	75 MG	60	TABS	30	DAYS					
58160020100120		Citalopram Hydrobromide Cap	30 MG	30	CAPS	30	DAYS					
581600201020		citalopram hydrobromide oral soln	10 MG/5ML	600	MLS	30	DAYS					
581800200075		desvenlafaxine tab er	100 MG; 50 MG	30	TABS	30	DAYS					
58180025106740		Duloxetine HCl Enteric Coated Pellets Cap 40 MG (Base Eq)	40 MG	90	CAPS	30	DAYS					
581600341020		escitalopram oxalate soln	5 MG/5ML	600	MLS	30	DAYS					
58160040006530		Fluoxetine HCl Cap Delayed Release 90 MG	90 MG	4	CAPS	28	DAYS					
58160040002020		Fluoxetine HCl Solution 20 MG/5ML	20 MG/5ML	600	MLS	30	DAYS					
58160040000310		Fluoxetine HCl Tab 10 MG	10 MG	30	TABS	30	DAYS					
58160040000320		Fluoxetine HCl Tab 20 MG	20 MG	120	TABS	30	DAYS					
58160040000360		Fluoxetine HCl Tab 60 MG	60 MG	30	TABS	30	DAYS					
581600451070		fluvoxamine maleate cap er	100 MG; 150 MG	60	CAPS	30	DAYS					
58160045100330		Fluvoxamine Maleate Tab 100 MG	100 MG	90	TABS	30	DAYS					
58160045100310		Fluvoxamine Maleate Tab 25 MG	25 MG	30	TABS	30	DAYS					
58160045100320		Fluvoxamine Maleate Tab 50 MG	50 MG	30	TABS	30	DAYS					
583000101003		maprotiline hcl tab	25 MG; 50 MG; 75 MG	90	TABS	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
58160070100140		Sertraline HCl Cap	200 MG	30	CAPS	30	DAYS					
58160070100130		Sertraline HCl Cap	150 MG	30	CAPS	30	DAYS					
58180090057520		Venlafaxine Besylate Tab ER	112.5 MG	30	TABS	30	DAYS					
581800901003		venlafaxine hcl tab	100 MG; 25 MG; 37.5 MG; 50 MG; 75 MG	90	TABS	30	DAYS					
58180090107530		Venlafaxine HCl Tab ER 24HR 150 MG (Base Equivalent)	150 MG	30	TABS	30	DAYS					
58180090107540		Venlafaxine HCl Tab ER 24HR 225 MG (Base Equivalent)	225 MG	30	TABS	30	DAYS					
58180090107510		Venlafaxine HCl Tab ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	TABS	30	DAYS					
58180090107520		Venlafaxine HCl Tab ER 24HR 75 MG (Base Equivalent)	75 MG	90	TABS	30	DAYS					
583000402075	Aplenzin	bupropion hbr tab er	174 MG; 348 MG; 522 MG	30	TABS	30	DAYS					
58999902300420	Auvelity	Dextromethorphan HBr-Bupropion HCl Tab ER	45 MG	60	TABS	30	DAYS					
581600201003	Celexa	Citalopram Hydrobromide Tab ; citalopram hydrobromide tab	10 MG; 20 MG; 40 MG	30	TABS	30	DAYS					
58180025106720	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 20 MG (Base Eq)	20 MG	60	CAPS	30	DAYS					
58180025106730	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 30 MG (Base Eq)	30 MG	60	CAPS	30	DAYS					
58180025106750	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 60 MG (Base Eq)	60 MG	60	CAPS	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
5818002510H120	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 20 MG (Base Eq)	20 MG	60	CAPS	30	DAYS					
5818002510H130	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 30 MG (Base Eq)	30 MG	60	CAPS	30	DAYS					
5818002510H140	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 40 MG (Base Eq)	40 MG	60	CAPS	30	DAYS					
5818002510H160	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 60 MG (Base Eq)	60 MG	60	CAPS	30	DAYS					
58180090107050	Effexor xr	Venlafaxine HCl Cap ER 24HR 150 MG (Base Equivalent)	150 MG	30	CAPS	30	DAYS					
58180090107020	Effexor xr	Venlafaxine HCl Cap ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	CAPS	30	DAYS					
58180090107030	Effexor xr	Venlafaxine HCl Cap ER 24HR 75 MG (Base Equivalent)	75 MG	90	CAPS	30	DAYS					
581800501070	Fetzima	levomilnacipran hcl cap er	120 MG; 20 MG; 40 MG; 80 MG	30	CAPS	30	DAYS					
5818005010B6	Fetzima titration pack	levomilnacipran hcl cap er	20 MG	28	CAPS	180	DAYS					
583000401075	Forfivo xl ; Wellbutrin xl	Bupropion HCl Tab ER; bupropion hcl tab er	150 MG; 300 MG; 450 MG	30	TABS	30	DAYS					
581600341003	Lexapro	Escitalopram Oxalate Tab; escitalopram oxalate tab	10 MG; 20 MG; 5 MG	30	TABS	30	DAYS					
581600600018	Paxil	paroxetine hcl oral susp	10 MG/5ML	900	MLS	30	DAYS					
58160060000310	Paxil	Paroxetine HCl Tab 10 MG	10 MG	30	TABS	30	DAYS					
58160060000320	Paxil	Paroxetine HCl Tab 20 MG	20 MG	30	TABS	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
58160060000330	Paxil	Paroxetine HCl Tab 30 MG	30 MG	60	TABS	30	DAYS					
58160060000340	Paxil	Paroxetine HCl Tab 40 MG	40 MG	30	TABS	30	DAYS					
58160060007520	Paxil cr	Paroxetine HCl Tab ER 24HR 12.5 MG	12.5 MG	30	TABS	30	DAYS					
58160060007530	Paxil cr	Paroxetine HCl Tab ER 24HR 25 MG	25 MG	60	TABS	30	DAYS					
58160060007540	Paxil cr	Paroxetine HCl Tab ER 24HR 37.5 MG	37.5 MG	60	TABS	30	DAYS					
58160060300310	Pexeva	Paroxetine Mesylate Tab 10 MG (Base Equiv)	10 MG	30	TABS	30	DAYS					
58160060300320	Pexeva	Paroxetine Mesylate Tab 20 MG (Base Equiv)	20 MG	30	TABS	30	DAYS					
58160060300330	Pexeva	Paroxetine Mesylate Tab 30 MG (Base Equiv)	30 MG	60	TABS	30	DAYS					
58160060300340	Pexeva	Paroxetine Mesylate Tab 40 MG (Base Equiv)	40 MG	30	TABS	30	DAYS					
581800202075	Pristiq	desvenlafaxine succinate tab er	100 MG; 25 MG; 50 MG	30	TABS	30	DAYS					
58160040000110	Prozac	Fluoxetine HCl Cap 10 MG	10 MG	30	CAPS	30	DAYS					
58160040000120	Prozac	Fluoxetine HCl Cap 20 MG	20 MG	120	CAPS	30	DAYS					
58160040000140	Prozac	Fluoxetine HCl Cap 40 MG	40 MG	60	CAPS	30	DAYS					
580300500003	Remeron	mirtazapine tab	15 MG; 30 MG; 45 MG; 7.5 MG	30	TABS	30	DAYS					
580300500072	Remeron soltab	mirtazapine orally disintegrating tab	15 MG; 30 MG; 45 MG	30	TABS	30	DAYS					
581200931003	Trintellix	vortioxetine hbr tab	10 MG; 20 MG; 5 MG	30	TABS	30	DAYS					
581200881003	Viibryd	vilazodone hcl tab	10 MG; 20 MG;	30	TABS	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
			40 MG									
581200881064	Viibryd starter pack	vilazodone hcl tab starter kit	10 MG	1	KIT	180	DAYS					
58120088106410	Viibryd starter pack	Vilazodone HCl Tab Starter Kit 10 (7) & 20 (23) MG	10 MG	1	KIT	180	DAYS					
583000401074	Wellbutrin sr	Bupropion HCl Tab ER ; bupropion hcl tab er	100 MG; 150 MG; 200 MG	60	TABS	30	DAYS					
58160070101320	Zoloft	Sertraline HCl Oral Concentrate for Solution 20 MG/ML	20 MG/ML	300	MLS	30	DAYS					
58160070100320	Zoloft	Sertraline HCl Tab 100 MG	100 MG	60	TABS	30	DAYS					
58160070100305	Zoloft	Sertraline HCl Tab 25 MG	25 MG	30	TABS	30	DAYS					
58160070100310	Zoloft	Sertraline HCl Tab 50 MG	50 MG	30	TABS	30	DAYS					

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. 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: 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: Atypical Antipsychotics

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
59250015002020		Aripiprazole Oral Solution 1 MG/ML	1 MG/ML	900	MLS	30	DAYS					
592500150072		aripiprazole orally disintegrating tab	10 MG; 15 MG	60	TABS	30	DAYS					
59152020007230		Clozapine Orally Disintegrating Tab 100 MG	100 MG	90	TABS	30	DAYS					
59152020007210		Clozapine Orally Disintegrating Tab 12.5 MG	12.5 MG	90	TABS	30	DAYS					
59152020007240		Clozapine Orally Disintegrating Tab 150 MG	150 MG	180	TABS	30	DAYS					
59152020007250		Clozapine Orally Disintegrating Tab 200 MG	200 MG	120	TABS	30	DAYS					
59152020007220		Clozapine Orally Disintegrating Tab 25 MG	25 MG	270	TABS	30	DAYS					
59153070100325		Quetiapine Fumarate Tab	150 MG	30	TABS	30	DAYS					
59070070007210		Risperidone Orally Disintegrating Tab 0.25 MG	0.25 MG	60	TABS	30	DAYS					
59070070007230		Risperidone Orally Disintegrating Tab 1 MG	1 MG	60	TABS	30	DAYS					
59070070007240		Risperidone Orally Disintegrating Tab 2 MG	2 MG	60	TABS	30	DAYS					
59070070007250		Risperidone Orally Disintegrating Tab 3 MG	3 MG	60	TABS	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
59070070007260		Risperidone Orally Disintegrating Tab 4 MG	4 MG	120	TABS	30	DAYS					
59070070000303		Risperidone Tab 0.25 MG	0.25 MG	60	TABS	30	DAYS					
592500150003	Abilify	aripiprazole tab	10 MG; 15 MG; 2 MG; 20 MG; 30 MG; 5 MG	30	TABS	30	DAYS					
59250015020340	Abilify mycite	Aripiprazole Tab	20 MG	30	TABS	30	DAYS					
59250015020320	Abilify mycite	Aripiprazole Tab	10 MG	30	TABS	30	DAYS					
59250015020350	Abilify mycite	Aripiprazole Tab	30 MG	30	TABS	30	DAYS					
59250015020330	Abilify mycite	Aripiprazole Tab	15 MG	30	TABS	30	DAYS					
59250015020310	Abilify mycite	Aripiprazole Tab	5 MG	30	TABS	30	DAYS					
59250015020305	Abilify mycite	Aripiprazole Tab	2 MG	30	TABS	30	DAYS					
5925001503B731	Abilify mycite maintenanc	Aripiprazole Tab	15 MG	30	TABS	30	DAYS					
5925001503B721	Abilify mycite maintenanc	Aripiprazole Tab	10 MG	30	TABS	30	DAYS					
5925001503B711	Abilify mycite maintenanc	Aripiprazole Tab	5 MG	30	TABS	30	DAYS					
5925001503B706	Abilify mycite maintenanc	Aripiprazole Tab	2 MG	30	TABS	30	DAYS					
5925001503B741	Abilify mycite maintenanc	Aripiprazole Tab	20 MG	30	TABS	30	DAYS					
5925001503B751	Abilify mycite maintenanc	Aripiprazole Tab	30 MG	30	TABS	30	DAYS					
5925001503B750	Abilify mycite starter ki	Aripiprazole Tab	30 MG	30	TABS	30	DAYS					
5925001503B740	Abilify mycite starter ki	Aripiprazole Tab	20 MG	30	TABS	30	DAYS					
5925001503B720	Abilify mycite starter ki	Aripiprazole Tab	10 MG	30	TABS	30	DAYS					
5925001503B705	Abilify mycite starter ki	Aripiprazole Tab	2 MG	30	TABS	30	DAYS					
5925001503B710	Abilify mycite starter ki	Aripiprazole Tab	5 MG	30	TABS	30	DAYS					
5925001503B730	Abilify mycite starter ki	Aripiprazole Tab	15 MG	30	TABS	30	DAYS					
594000224001	Caplyta	lumateperone tosylate cap	10.5 MG; 21 MG; 42 MG	30	CAPS	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
59152020000330	Clozaril	Clozapine Tab 100 MG	100 MG	270	TABS	30	DAYS					
59152020000340	Clozaril	Clozapine Tab 200 MG	200 MG	120	TABS	30	DAYS					
59152020000320	Clozaril	Clozapine Tab 25 MG	25 MG	90	TABS	30	DAYS					
59152020000325	Clozaril	Clozapine Tab 50 MG	50 MG	90	TABS	30	DAYS					
590700350003	Fanapt	iloperidone tab	1 MG; 10 MG; 12 MG; 2 MG; 4 MG; 6 MG; 8 MG	60	TABS	30	DAYS					
59070035006320	Fanapt titration pack	Iloperidone Tab 1 MG & 2 MG & 4 MG & 6 MG Titration Pak	1 MG	1	PACK	180	DAYS					
594000851001	Geodon	ziprasidone hcl cap	20 MG; 40 MG; 60 MG; 80 MG	60	CAPS	30	DAYS					
59400085202120	Geodon	Ziprasidone Mesylate For Inj 20 MG (Base Equivalent)	20 MG	60	VIALS	30	DAYS					
59070050007505	Invega	Paliperidone Tab ER 24HR 1.5 MG	1.5 MG	30	TABS	30	DAYS					
59070050007510	Invega	Paliperidone Tab ER 24HR 3 MG	3 MG	30	TABS	30	DAYS					
59070050007520	Invega	Paliperidone Tab ER 24HR 6 MG	6 MG	60	TABS	30	DAYS					
59070050007530	Invega	Paliperidone Tab ER 24HR 9 MG	9 MG	30	TABS	30	DAYS					
59400023100350	Latuda	Lurasidone HCl Tab 120 MG	120 MG	30	TABS	30	DAYS					
59400023100310	Latuda	Lurasidone HCl Tab 20 MG	20 MG	30	TABS	30	DAYS					
59400023100320	Latuda	Lurasidone HCl Tab 40 MG	40 MG	30	TABS	30	DAYS					
59400023100330	Latuda	Lurasidone HCl Tab 60 MG	60 MG	30	TABS	30	DAYS					
59400023100340	Latuda	Lurasidone HCl Tab 80 MG	80 MG	60	TABS	30	DAYS					
62994802500340	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	20 MG-10 MG	30	TABS	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
62994802500320	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	10 MG-10 MG	30	TABS	30	DAYS					
62994802500310	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	5 MG-10 MG	30	TABS	30	DAYS					
62994802500330	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	15 MG-10 MG	30	TABS	30	DAYS					
592500200003	Rexulti	brexpiprazole tab	0.25 MG; 0.5 MG; 1 MG; 2 MG; 3 MG; 4 MG	30	TABS	30	DAYS					
59070070002010	Risperdal	Risperidone Soln 1 MG/ML	1 MG/ML	480	MLS	30	DAYS					
59070070000306	Risperdal	Risperidone Tab 0.5 MG	0.5 MG	60	TABS	30	DAYS					
59070070000310	Risperdal	Risperidone Tab 1 MG	1 MG	60	TABS	30	DAYS					
59070070000320	Risperdal	Risperidone Tab 2 MG	2 MG	60	TABS	30	DAYS					
59070070000330	Risperdal	Risperidone Tab 3 MG	3 MG	60	TABS	30	DAYS					
59070070000340	Risperdal	Risperidone Tab 4 MG	4 MG	120	TABS	30	DAYS					
59070070007220	Risperdal m-tab	Risperidone Orally Disintegrating Tab 0.5 MG	0.5 MG	60	TABS	30	DAYS					
591550151007	Saphris	Asenapine Maleate SL Tab; asenapine maleate sl tab	10 MG; 2.5 MG; 5 MG	60	TABS	30	DAYS					
591550150085	Secuado	asenapine td patch	3.8 MG/24HR; 5.7 MG/24HR; 7.6 MG/24HR	30	PATCHS	30	DAYS					
59153070100320	Seroquel	Quetiapine Fumarate Tab 100 MG	100 MG	90	TABS	30	DAYS					
59153070100330	Seroquel	Quetiapine Fumarate Tab 200 MG	200 MG	90	TABS	30	DAYS					
59153070100310	Seroquel	Quetiapine Fumarate Tab 25 MG	25 MG	90	TABS	30	DAYS					
59153070100340	Seroquel	Quetiapine Fumarate Tab 300 MG	300 MG	60	TABS	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
59153070100350	Seroquel	Quetiapine Fumarate Tab 400 MG	400 MG	60	TABS	30	DAYS					
59153070100314	Seroquel	Quetiapine Fumarate Tab 50 MG	50 MG	90	TABS	30	DAYS					
59153070107515	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 150 MG	150 MG	30	TABS	30	DAYS					
59153070107520	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 200 MG	200 MG	30	TABS	30	DAYS					
59153070107530	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 300 MG	300 MG	60	TABS	30	DAYS					
59153070107540	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 400 MG	400 MG	60	TABS	30	DAYS					
59153070107505	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 50 MG	50 MG	60	TABS	30	DAYS					
591520200018	Versacloz	clozapine susp	50 MG/ML	540	MLS	30	DAYS					
594000181001	Vraylar	cariprazine hcl cap	1.5 MG; 3 MG; 4.5 MG; 6 MG	30	CAPS	30	DAYS					
5940001810B220	Vraylar	Cariprazine HCl Cap Therapy Pack 1.5 MG (1) & 3 MG (6)	1.5 MG-3 MG	1	PACK	180	DAYS					
59157060002120	Zyprexa	Olanzapine For IM Inj 10 MG	10 MG	60	VIALS	30	DAYS					
591570600003	Zyprexa	Olanzapine Tab; olanzapine tab	10 MG; 15 MG; 2.5 MG; 20 MG; 5 MG; 7.5 MG	30	TABS	30	DAYS					
591570600072	Zyprexa zydis	olanzapine orally disintegrating tab	10 MG; 15 MG; 20 MG; 5 MG	30	TABS	30	DAYS					

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. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:

Module	Clinical Criteria for Approval
	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: 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: Atypical Antipsychotics – Extended Maintenance Agents

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
5925001500E4	Abilify maintena	aripiprazole im for er susp prefilled syringe	300 MG; 400 MG	1	SYRNG	28	DAYS					
5925001500G2	Abilify maintena	aripiprazole im for extended release susp	300 MG; 400 MG	1	VIAL	28	DAYS					
5925001520E450	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 1064 MG/3.9ML	1064 MG/3.9ML	1	SYRNG	56	DAYS					
5925001520E420	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 441 MG/1.6ML	441 MG/1.6ML	1	SYRNG	28	DAYS					
5925001520E430	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 662 MG/2.4ML	662 MG/2.4ML	1	SYRNG	28	DAYS					
5925001520E440	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled	882 MG/3.2ML	1	SYRNG	28	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
		Syr 882 MG/3.2ML										
5925001520E435	Aristada initio	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 675 MG/2.4ML	675 MG/2.4ML	1	KIT	180	DAYS					
5907005010E675	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	1	SYRNG	180	DAYS					
5907005010E670	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	1	SYRNG	180	DAYS					
5907005010E632	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	1	KIT	28	DAYS					
5907005010E635	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	1	KIT	28	DAYS					
5907005010E638	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5ML	1	KIT	28	DAYS					
5907005010E626	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	1	KIT	28	DAYS					
5907005010E629	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	1	KIT	28	DAYS					
5907005010E643	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88ML	1	SYRNG	84	DAYS					
5907005010E647	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32ML	1	SYRNG	84	DAYS					
5907005010E651	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	1	SYRNG	84	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
5907005010E655	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63ML	1	SYRNG	84	DAYS					
5907007000E4	Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG; 90 MG	1	KIT	28	DAYS					
5907007010G2	Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG; 25 MG; 37.5 MG; 50 MG	2	VIALS	28	DAYS					
59157060101950	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 210 MG (Base Eq)	210 MG	2	VIALS	28	DAYS					
59157060101960	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 300 MG (Base Eq)	300 MG	2	VIALS	28	DAYS					
59157060101970	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 405 MG (Base Eq)	405 MG	1	VIAL	28	DAYS					

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. 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: 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**

Module	Clinical Criteria for Approval
	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: Combination Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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
349987021003	Consensi	amlodipine besylate-celecoxib tab	10 MG; 2.5 MG; 5 MG	30	TABS	30	DAYS					
661099023203	Duexis	ibuprofen-famotidine tab	800 MG	90	TABS	30	DAYS					
661099024406	Vimovo	naproxen-esomeprazole magnesium tab dr	375 MG; 500 MG	60	TABS	30	DAYS					
851599020406	Yosprala	Aspirin-Omeprazole Tab Delayed Release; aspirin-omeprazole tab delayed release	325 MG; 81 MG	30	TABS	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. For Consensi, BOTH of the following: 1. The patient has a diagnosis of hypertension **AND** 2. The patient has a diagnosis of osteoarthritis **OR** B. BOTH of the following: 1. ONE of the following: A. For Duexis or ibuprofen/famotidine requests, the patient has a diagnosis of at least ONE of the following: 1. Rheumatoid arthritis **OR** 2. Osteoarthritis **OR** B. For Vimovo or naproxen/esomeprazole requests, the patient has a diagnosis of at least ONE of the following: 1. Osteoarthritis in adults **OR** 2. Rheumatoid arthritis in adults **OR** 3. Ankylosing spondylitis in adults **OR** 4. Juvenile idiopathic arthritis (JIA) in adolescents weighing greater than or equal to 38 kg **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers:

Module	Clinical Criteria for Approval
	A. Age greater than or equal to 65 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID-related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **OR** C. For Yosprala or aspirin/omeprazole requests, BOTH of the following: 1. The patient has an indication of use of at least ONE of the following: A. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli **OR** B. Reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with previous MI or unstable angina pectoris **OR** C. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris **OR** D. Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 55 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID–related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **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. ONE of the following: A. Information has been provided that use of the individual ingredients within the target combination agent, as separate dosage forms, is not clinically appropriate for the patient **OR** B. BOTH of the following: 1. The patient’s medication history includes use of the individual ingredients within the target combination agent, as separate dosage forms, as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the individual ingredients within the target combination agent, as separate dosage forms **AND** 2. ONE of the following: A. The individual ingredients within the target combination agent, as separate dosage forms 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 use of the individual ingredients within the target combination agent, as separate dosage forms **OR**

Module	Clinical Criteria for Approval
	C. 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 currencly 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** D. The prescriber has provided documentation that the individual ingredients within the target combination agent, as separate dosage forms, 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** 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
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** 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: Gabapentin Extended-Release (ER)

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
62540030000325	Gralise	gabapentin (once-daily) tab	450 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.			
62540030000345	Gralise	gabapentin (once-daily) tab	750 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.			
62540030000360	Gralise	gabapentin (once-daily) tab	900 MG	60	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.			
62540030000320	Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will			

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
									be approved for 1 month only.			
62540030000330	Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	90	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.			
62560030200420	Horizant	Gabapentin Enacarbil Tab ER 300 MG	300 MG	60	Tablets	30	DAYS					
62560030200430	Horizant	Gabapentin Enacarbil Tab ER 600 MG	600 MG	60	Tablets	30	DAYS					

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. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only **OR** 3. 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: 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: Galafold (migalastat)

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
30903650100120	Galafold	Migalastat HCl Cap 123 MG (Base Equivalent)	123 MG	14	CAPS	28	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 Fabry disease AND BOTH of the following: A. The diagnosis was confirmed by mutation in the galactosidase alpha (*GLA*) gene **AND** B. The patient has a confirmed amenable *GLA* variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at http://www.galafoldamenabilitytable.us/reference) **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., endocrinologist, geneticist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The prescriber has assessed current status of ALL of the following: renal function (e.g., proteinuria, glomerular filtration rate [GFR]), cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities), ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy), peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function), and gastrointestinal involvement (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND** 5. The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Fabrazyme) for the requested indication **AND** 6. 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 improvements or stabilization with the requested agent as indicated by ONE of the following: A. Renal function (e.g., proteinuria, glomerular filtration rate [GFR]) **OR** B. Cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities) **OR**

Module	Clinical Criteria for Approval
	C. Ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy) **OR** D. Peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function) **OR** E. Gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) or the prescriber 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 enzyme replacement therapy (ERT) (e.g., Fabrazyme) for the requested indication **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
	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 **Length of Approval:** Initial - 6 months; Renewal - 12 months

• Program Summary: Growth Hormone

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	3010	Genotropin; Genotropin miniquick; Humatrope; Norditropin flexpro; Nutropin aq nuspin 10; Nutropin aq nuspin 20; Nutropin aq nuspin 5; Omnitrope; Saizen; Saizenprep reconstitution; Serostim; Skytrofa; Zomacton; Zorbtive	Somatropin For Inj; lonapegsomatropin-tcgd for subcutaneous inj cartridge; lonapegsomatropin-tcgd for subcutaneous inj cartridge; somatropin (non-refrigerated) for inj; somatropin (non-refrigerated) for subcutaneous inj; somatropin for inj; somatropin for inj cartridge; somatropin for subcutaneous inj; somatropin for subcutaneous inj cartridge;	0.2 MG; 0.4 MG; 0.6 MG; 0.8 MG; 1 MG; 1.2MG; 1.4 MG; 1.6 MG; 1.8 MG; 10; 10 MG; 10 MG/1.5ML; 10 MG/2ML; 11 MG; 12 MG; 13.3 MG; 15 MG/1.5ML; 2 MG; 20 MG/2ML; 24 MG; 3 MG; 3.6 MG; 30 MG/3ML; 4 MG; 4.3 MG; 5 MG; 5 MG/1.5ML; 5 MG/2ML; 5.2 MG; 5.8 MG; 6 MG; 6.3 MG; 7.6 MG; 8.8 MG; 9.1 MG	M; N; O; Y				

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
			somatropin for subcutaneous inj prefilled syr; somatropin solution cartridge; somatropin solution pen-injector						

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adult	**TARGET AGENTS:** **For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ** Omnitrope® (somatropin) Genotropin® , Genotropin® MiniQuick (somatropin) Humatrope® (somatropin) Norditropin FlexPro® (somatropin) Nutropin AQ NuSpin® (somatropin) Saizen®, Saizenprep® (somatropin) Serostim® (somatropin) Skytrofa™ (lonapegsomatropin-tcgd) Zomacton® (somatropin) Zorbtive® (somatropin) **Adults – Initial Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The request is for a preferred agent or Serostim or Zorbtive **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided information that ALL preferred agents 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** 2. The patient is an adult (as defined by the prescriber) **AND** 3. The patient has ONE of the following diagnoses: A. If the request is for Serostim, the patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. BOTH of the following: A. ONE of the following: 1. The patient has had weight loss that meets ONE of the following: A. 10% unintentional weight loss over 12 months **OR** B. 7.5% unintentional weight loss over 6 months **OR** 2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR** 3. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m2 **OR** 4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m2 **OR** 5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR** 6. The patient's BMI is less than 20 kg/m2 **AND** B. All other causes of weight loss have been ruled out **OR** B. If the request is for Zorbtive, the patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR** 2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following: A. Organic hypothalamic-pituitary disease **OR** B. Pituitary structural lesion or trauma **OR** C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR** 3. The patient has an established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary **OR** 4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR**

Module	Clinical Criteria for Approval
	5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** SBS: 4 weeks AIDS wasting/cachexia: 12 weeks Any other indication: 12 months **Adults – Renewal Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND** 2. ONE of the following: A. The request is for a preferred agent or Serostim or Zorbtive **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided information that ALL preferred agents 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 is an adult (as defined by the prescriber) **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
1. The patient is currently treated with antiretroviral therapy AND
2. The patient will continue antiretroviral therapy in combination with the requested agent AND
3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) OR
C. The patient has any other diagnosis AND BOTH of the following:
1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose AND
2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent AND
6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient’s diagnosis AND
7. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication AND
8. The patient is being monitored for adverse effects of GH

Length of Approval:
<table>
<tr><td>SBS</td><td>4 weeks</td></tr>
<tr><td>AIDS wasting/cachexia</td><td>12 weeks</td></tr>
<tr><td>Any other indication</td><td>12 months</td></tr>
</table>
</td></tr>
<tr><td>Child</td><td>
<table>
<tr><th>TARGET AGENTS:
For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ</th></tr>
<tr><td>Omnitrope® (somatropin)
Genotropin® , Genotropin® MiniQuick (somatropin)
Humatrope® (somatropin)
Norditropin FlexPro® (somatropin)
Nutropin AQ NuSpin® (somatropin)
Saizen®, Saizenprep® (somatropin)
Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Zomacton® (somatropin)
Zorbtive® (somatropin)</td></tr>
</table>

Growth Hormone (GH) products will be approved as below.

For Children – Initial Evaluation when ALL of the following are met:
1. ONE of the following:
A. The request is for a preferred agent or Zorbtive or Serostim OR
B. ONE of the following:
1. The patient’s medication history includes two preferred agents AND ONE of the following:
A. The patient has had an inadequate response to two preferred agents OR
</td></tr>
</table>

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided information that ALL preferred agents 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** 2. The patient is a child (as defined by the prescriber) **AND** 3. The patient has ONE of the following diagnoses: A. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L **AND** 3. ONE of the following: A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **OR** B. Deficiency of at least one additional pituitary hormone **OR** B. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a growth hormone (GH) concentration less than 20 mcg/L **AND** 3. The patient does not have a known metabolic disorder **AND** 4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) **OR** C. The patient has a diagnosis of Turner syndrome **OR** D. The patient has a diagnosis of Noonan syndrome **OR** E. The patient has a diagnosis of Prader-Willi syndrome **OR** F. The patient has a diagnosis of SHOX gene deficiency **OR** G. If the request is for Zorbtive, the patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR**

Module	Clinical Criteria for Approval
	I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following: 1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND** 2. Other etiologies for growth impairment have been addressed **OR** J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following: 1. The patient is 2 years of age or older **AND** 2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND** 3. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex **OR** K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: 1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND** 2. The patient has open epiphyses **AND** 3. ONE of the following: A. The patient has a predicted adult height that is below the normal range AND ONE of the following: 1. The patient's sex is male and predicted adult height is less than 63 inches **OR** 2. The patient's sex is female and predicted adult height is less than 59 inches **OR** B. The patient is more than 2 SD below their mid-parental target height **AND** 4. BOTH of the following: A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND** B. The patient does NOT have a diagnosis of CDGP **OR** L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR**

Module	Clinical Criteria for Approval
	B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 4 weeks for SBS 12 months for other indications **Children – Renewal Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. ONE of the following: A. The request is for a preferred agent or Zorbtive or Serostim **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided information that ALL preferred agents 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 is a child (as defined by the prescriber) **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** B. The patient has a diagnosis of ISS and BOTH of the following: 1. Growth velocity is greater than 2 cm/year **AND** 2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** C. The patient has any other diagnosis AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased or height velocity has improved since initiation or last GH approval **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 4 weeks for SBS 12 months for other indications

• Program Summary: Jynarque (tolvaptan)

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
30454060000320	Jynarque	tolvaptan tab	15 MG	60	TABS	30	DAYS			59148-0082-13		
30454060000330	Jynarque	tolvaptan tab	30 MG	30	TABS	30	DAYS			59148-0083-13		
3045406000B710	Jynarque	Tolvaptan Tab Therapy Pack 15 MG	15 MG	56	TABS	28	DAYS					
3045406000B720	Jynarque	Tolvaptan Tab Therapy Pack 30 & 15 MG	30 MG-15 MG	56	TABS	28	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
3045406000B725	Jynarque	Tolvaptan Tab Therapy Pack 45 & 15 MG	45 MG-15 MG	56	TABS	28	DAYS					
3045406000B735	Jynarque	Tolvaptan Tab Therapy Pack 60 & 30 MG	60 MG-30 MG	56	TABS	28	DAYS					
3045406000B745	Jynarque	Tolvaptan Tab Therapy Pack 90 & 30 MG	90 MG-30 MG	56	TABS	28	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 autosomal dominant polycystic kidney disease (ADPKD) confirmed by ONE of the following: A. Ultrasonography **OR** B. MRI or CT scan **OR** C. Genetic testing **AND** 2. ONE of the following: A. The patient has typical (Class 1) ADPKD AND has been classified as 1C, 1D, or 1E using the Mayo ADPKD Classification assessment **OR** B. The patient has kidney length (KL) greater than 16.5 cm bilaterally **OR** C. The patient has had a sequential increase of greater than 5% annually in height adjusted total kidney volume (htTKV) on imaging **OR** D. The prescriber has determined the patient has disease progression (e.g., rapid decline in eGFR defined as eGFR greater than 2.5 mL/min/1.73 m^2) **OR** E. There is information indicating the patient's ADPKD is rapidly progressing **AND** 3. If the patient has an FDA labeled 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 patient will NOT be using the requested agent in combination with another tolvaptan agent **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 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. **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 **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **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**

Module	Clinical Criteria for Approval
	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.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**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 **Length of Approval:** 12 months

• Program Summary: Low Molecular Weight Heparins and Arixtra

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
83101020102012		Enoxaparin Sodium Inj 30 MG/0.3ML	30 MG/0.3ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
83101020102014		Enoxaparin Sodium Inj 60 MG/0.6ML	60 MG/0.6ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient			

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
									requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
83101020102015		Enoxaparin Sodium Inj 80 MG/0.8ML	80 MG/0.8ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
83103030102045	Arixtra	Fondaparinux Sodium Subcutaneous Inj 10 MG/0.8ML	10 MG/0.8ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
83103030102020	Arixtra	Fondaparinux Sodium Subcutaneous Inj 2.5 MG/0.5ML	2.5 MG/0.5ML	30	SYRNGS	90	DAYS	a single course of therapy	"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			

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
8310303010 2035	Arixtra	Fondaparinux Sodium Subcutaneous Inj 5 MG/0.4ML	5 MG/0.4ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310303010 2040	Arixtra	Fondaparinux Sodium Subcutaneous Inj 7.5 MG/0.6ML	7.5 MG/0.6ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer."			
8310101010 2017	Fragmin	dalteparin sodium inj 2500 unit/ml	10000 UNIT/4ML	30	VIALS	90	DAYS					
8310101010 2080	Fragmin	Dalteparin Sodium Inj 95000 Unit/3.8ML	95000 UNIT/3.8ML	10	VIALS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310101010 E520	Fragmin	Dalteparin Sodium Soln Prefilled Syr	7500 UNIT/0.3ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of			

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
									thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310101010E530	Fragmin	Dalteparin Sodium Soln Prefilled Syr	10000 UNIT/ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310101010E550	Fragmin	Dalteparin Sodium Soln Prefilled Syr	18000 UNT/0.72ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310101010E505	Fragmin	Dalteparin Sodium Soln Prefilled Syr	2500 UNIT/0.2ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR			

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
									2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310101010E515	Fragmin	Dalteparin Sodium Soln Prefilled Syr	5000 UNIT/0.2ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310101010E535	Fragmin	Dalteparin Sodium Soln Prefilled Syr	12500 UNIT/0.5ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310101010E540	Fragmin	Dalteparin Sodium Soln Prefilled Syr	15000 UNIT/0.6ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND			

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
									the patient has cancer. "			
83101020102050	Lovenox	Enoxaparin Sodium Inj 300 MG/3ML	300 MG/3ML	10	VIALS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310102010E535	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	80 MG/0.8ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310102010E530	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	60 MG/0.6ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310102010E520	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	30 MG/0.3ML	30	SYRNGS	90	DAYS		1. The patient requires extended treatment for primary			

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
									or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer.			
8310102010E525	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	40 MG/0.4ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310102010E560	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	120 MG/0.8ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310102010E565	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	150 MG/ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended			

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
									prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			
8310102010E540	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	100 MG/ML	30	SYRNGS	90	DAYS		"1. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium. OR 2. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) AND the patient has cancer. "			

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. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium **OR** 3. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) **AND** the patient has cancer **OR** 4. 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: 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: Lyrica and Savella

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
72600057000125	Lyrica	Pregabalin Cap 100 MG	100 MG	90	CAPS	30	DAYS					
72600057000135	Lyrica	Pregabalin Cap 150 MG	150 MG	90	CAPS	30	DAYS					
72600057000145	Lyrica	Pregabalin Cap 200 MG	200 MG	90	CAPS	30	DAYS					
72600057000150	Lyrica	Pregabalin Cap 225 MG	225 MG	60	CAPS	30	DAYS					
72600057000110	Lyrica	Pregabalin Cap 25 MG	25 MG	90	CAPS	30	DAYS					
72600057000160	Lyrica	Pregabalin Cap 300 MG	300 MG	60	CAPS	30	DAYS					
72600057000115	Lyrica	Pregabalin Cap 50 MG	50 MG	90	CAPS	30	DAYS					
72600057000120	Lyrica	Pregabalin Cap 75 MG	75 MG	90	CAPS	30	DAYS					
72600057002020	Lyrica	Pregabalin Soln 20 MG/ML	20 MG/ML	900	MLS	30	DAYS					
62540060007530	Lyrica cr	Pregabalin Tab ER 24HR 165 MG	165 MG	30	TABS	30	DAYS					
62540060007540	Lyrica cr	Pregabalin Tab ER 24HR 330 MG	330 MG	60	TABS	30	DAYS					
62540060007520	Lyrica cr	Pregabalin Tab ER 24HR 82.5 MG	82.5 MG	30	TABS	30	DAYS					
625040501003	Savella	milnacipran hcl tab	100 MG; 12.5 MG; 25 MG; 50 MG	60	TABS	30	DAYS					
62504050106320	Savella titration pack	Milnacipran HCl Tab 12.5 MG (5) & 25 MG (8) & 50 MG (42) Pak	12.5 MG-25 MG-50 MG	1	PACK	180	DAYS					

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. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:

Module	Clinical Criteria for Approval
	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: 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: Lyrica CR - Retired

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

This program is retired effective 7/1/2023. The Lyrica CR product has moved to the Lyrica and Savella QL program.

• Program Summary: Selective Serotonin Inverse Agonist (SSIA)

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
59400028200120	Nuplazid	Pimavanserin Tartrate Cap 34 MG (Base Equivalent)	34 MG	30	CAPS	30	DAYS					
59400028200310	Nuplazid	Pimavanserin Tartrate Tab 10 MG (Base Equivalent)	10 MG	30	TABS	30	DAYS					

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**

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 **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: Substrate Reduction Therapy

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
82700040600120	Cerdelga	Eliglustat Tartrate Cap 84 MG (Base Equivalent)	84 MG	60	CAPS	30	DAYS					
82700070000120	Zavesca	Miglustat Cap 100 MG	100 MG	90	CAPS	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION 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 Gaucher disease type 1 (GD1) **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 patient does NOT have any neuronopathic symptoms indicative of Gaucher disease type 2 or type 3 [e.g., bulbar signs (e.g., stridor, strabismus, swallowing difficulty), pyramidal signs (e.g., opisthotonos, head retroflexion, spasticity, trismus), oculomotor apraxia, tonic-clonic seizures, myoclonic epilepsy, dementia, ataxia] **AND** 4. ONE of the following: A. The patient has baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in fibroblasts, leukocytes, or other nucleated cells **OR** B. Genetic analysis confirmed two (2) pathogenic alleles in the glucocerebrosidase (*GBA*) gene **AND** 5. The prescriber has assessed baseline (prior to therapy for the requested indication) status of hemoglobin level, platelet count, liver volume, and spleen volume **AND**

Module	Clinical Criteria for Approval

6. The patient has at least ONE of the following clinical presentations at baseline (prior to therapy for the requested indication):
   A. Anemia defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender **OR**
   B. Thrombocytopenia (platelet count less than 100,000/microliter on at least 2 measurements) **OR**
   C. Hepatomegaly **OR**
   D. Splenomegaly **OR**
   E. Growth failure (i.e., growth velocity is below the standard mean for age) **OR**
   F. Evidence of bone disease with other causes ruled out **AND**
7. If the requested agent is Cerdelga or eliglustat, the patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM), as detected by an FDA-cleared test for determining CYP2D6 genotype **AND**
8. If the requested agent is Zavesca or miglustat, enzyme replacement therapy (ERT) is NOT a therapeutic option (e.g., due to allergy, hypersensitivity, poor venous access, previous ERT failure) **AND**
9. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient's medication history includes use of the generic equivalent **OR**
   B. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Zavesca	miglustat

   F. 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**
   G. The prescriber has provided documentation that the generic equivalent 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**
10. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
11. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) for the requested indication **AND**
12. 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 improvement or stabilization with the requested agent as indicated by ONE of the following: A. Spleen volume **OR** B. Hemoglobin level **OR** C. Liver volume **OR** D. Platelet count (sufficient to decrease the risk of bleeding) **OR** E. Growth **OR** F. Bone pain or crisis **AND** 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: A. The patient's medication history includes use of the generic equivalent **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried the generic equivalent **AND** 2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR** D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** **Brand** / **Generic Equivalent** Zavesca / miglustat F. 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** G. The prescriber has provided documentation that the generic equivalent 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** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) for the requested indication **AND** 6. 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
PA	**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

• Program Summary: Urea Cycle Disorders

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	309080600029	Buphenyl	sodium phenylbutyrate oral powder	3 GM/TSP	M ; N ; O ; Y				
	309080600003	Buphenyl	sodium phenylbutyrate tab	500 MG	M ; N ; O ; Y				
	309080600089	Pheburane	sodium phenylbutyrate oral pellets	483 MG/GM	M ; N ; O ; Y				09-26-2022
	309080300009	Ravicti	glycerol phenylbutyrate liquid	1.1 GM/ML	M ; N ; O ; Y				

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 hyperammonemia AND ALL of the following: A. The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 micromol/L (greater than 260 micrograms/dL) or higher; Older child or adult: plasma ammonia level greater than 100 micromol/L (175 micrograms/dL)] **AND** B. The patient has a normal anion gap **AND** C. The patient has a normal blood glucose level **AND** 2. The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by enzyme analysis OR genetic testing: A. carbamoyl phosphate synthetase I deficiency [CPSID] B. ornithine transcarbamylase deficiency [OTCD] C. argininosuccinic acid synthetase deficiency [ASSD]

Module	Clinical Criteria for Approval
	D. argininosuccinic acid lyase deficiency [ASLD] E. arginase deficiency [ARG1D] **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, when clinically appropriate, essential amino acid supplementation **AND** 5. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 6. ONE of the following: A. If the requested agent is Buphenyl or Pheburane, then ONE of the following: 1. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 2. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 3. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **OR** 4. BOTH of the following: A. The patient's medication history includes generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action **AND** B. ONE of the following: 1. Generic sodium phenylbutyrate or drug in the same pharmacological class with the same mechanism of action 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 generic sodium phenylbutyrate **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that generic sodium phenylbutyrate 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 **OR** B. If the requested agent is Ravicti, ONE of the following: 1. The patient's medication history includes generic sodium phenylbutyrate AND Pheburane AND ONE of the following: A. The patient has had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sodium phenylbutyrate AND Pheburane **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **OR**

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	4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic sodium phenylbutyrate AND Pheburane 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) 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 **AND** 9. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months **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., plasma ammonia level within the normal range) **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) 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 **AND** 7. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Vijoice (alpelisib)

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
9948601000B740	Vijoice	Alpelisib (PROS) Pak	200 MG	56	TABS	28	DAYS					
9948601000B720	Vijoice	Alpelisib (PROS) Tab Therapy Pack	50 MG	28	TABS	28	DAYS					
9948601000B730	Vijoice	Alpelisib (PROS) Tab Therapy Pack	125 MG	28	TABS	28	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 PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by ALL of the following: A. Presence of somatic PIK3CA mutation **AND** B. Congenital or early childhood onset **AND** C. Overgrowth sporadic and mosaic **AND** D. ONE of the following: 1. The patient has at least TWO of the following features: A. Overgrowth B. Vascular malformations C. Epidermal nevus **OR** 2. The patient has at least ONE of the following features: A. Large isolated lymphatic malformations B. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs C. Truncal adipose overgrowth D. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia E. Epidermal nevus F. Seborrheic keratoses G. Benign lichenoid keratoses **AND** 2. The patient has severe manifestations of PROS that requires systemic therapy **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 experienced in PROS or the prescriber has consulted with a specialist experienced in PROS **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 **AND** 3. The patient has NOT had disease progression (e.g., increase in lesion number, increase in lesion volume) with the requested agent (medical records required) **AND** 4. The prescriber is a specialist experienced in PROS or the prescriber has consulted with a specialist experienced in PROS **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.

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 **Length of Approval**: 6 months for initial; 12 months for renewal

• Program Summary: Zokinvy

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
99463045000120	Zokinvy	Lonafarnib Cap	50 MG	120	CAPS	30	DAYS					
99463045000130	Zokinvy	Lonafarnib Cap	75 MG	120	CAPS	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) **AND** 2. Genetic testing has confirmed a pathogenic variant in the *LMNA* gene that results in production of progerin (medical record required) **OR** B. The patient has a processing-deficient progeroid laminopathy AND ONE of the following: 1. Genetic testing has confirmed heterozygous *LMNA* mutation with progerin-like protein accumulation (medical record required) **OR** 2. Genetic testing has confirmed homozygous or compound heterozygous *ZMPSTE24* mutations (medical record required) **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 patient has a body surface area (BSA) of greater than or equal to 0.39 m^2 **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	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. **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 **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist) 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
	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 **Length of Approval:** 12 months