MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: April 1, 2024 Notification Posted: March 15, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Inhaled Antibiotics Duplicate 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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
07000070002530	Bethkis	Tobramycin Nebu Soln 300 MG/4ML	300 MG/4ML	56	Ampules	56	DAYS				
161400104021	Cayston	aztreonam lysine for inhal soln	75 MG	84	Vials	56	DAYS				
07000070002520	Kitabis pak; Tobi	Tobramycin Nebu Soln 300 MG/5ML	300 MG/5ML	56	Ampules	56	DAYS				
070000700001	Tobi podhaler	tobramycin inhal cap	28 MG	28	Blisters	56	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) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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: Rivfloza (nedosiran)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
TBD	Rivfloza 128 mg single-dose prefilled syringe	nedosiran		1	Syringe	30	DAYS				
TBD	Rivfloza 160 mg single-dose prefilled syringe	nedosiran		1	Syringe	30	DAYS				
TBD	Rivfloza 80 mg single-dose vial	nedosiran		2	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by ONE of the following: A. Genetic testing of the *AGXT* gene indicates a pathogenic mutation **OR** B. Liver biopsy demonstrates absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity **AND** 2. The requested agent will be used to lower urinary oxalate levels **AND** 3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following: A. The patient's medication history includes potassium citrate or sodium citrate **AND** ONE of the following: 1. The patient has had an inadequate response to potassium citrate or sodium citrate **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH potassium citrate and sodium citrate **OR** B. The patient has an intolerance or hypersensitivity to potassium citrate or sodium citrate therapy **OR** C. The patient has an FDA labeled contraindication to BOTH potassium citrate AND sodium citrate **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH potassium citrate and sodium citrate 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 **AND** 6. ONE of the following: A. The patient's medication history includes pyridoxine (vitamin B6) for at least 3 months **AND** ONE of the following: 1. The patient has had an inadequate response to pyridoxine (vitamin B6) (inadequate response defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR** 2. The patient is responsive to pyridoxine (vitamin B6) (responsive defined as greater than 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **AND** will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR** 3. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over pyridoxine (vitamin B6) **OR** B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR** C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that pyridoxine (vitamin B6) 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 **AND** 7. The patient has not received a kidney or liver transplant **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 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., decrease in urinary oxalate levels) **AND** 3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND** 4. ONE of the following: A. The patient's medication history includes pyridoxine (vitamin B6) **AND** ONE of the following: 1. The patient will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR** 2. The patient has had an inadequate response to pyridoxine (vitamin B6) (inadequate response defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR** 3. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over pyridoxine (vitamin B6) **OR** B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR** C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that pyridoxine (vitamin B6) 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 **AND** 5. The patient has not received a kidney or liver transplant **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

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) exceeds 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 (Initial); 12 months (Renewal)

• Program Summary: Xdemvy

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
86106050002020	Xdemvy	lotilaner ophth soln	0.25 %	1	Bottle	50	DAYS				

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: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 2 months

• Program Summary: Zilbrysq (zilucoplan)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
TBD	Zilbrysq 16.6 mg/0.416 mL	zilucoplan		28	Syringes	28	DAYS				
TBD	Zilbrysq 23 mg/0.574 mL	zilucoplan		28	Syringes	28	DAYS				
TBD	Zilbrysq 32.4 mg/0.81 mL	zilucoplan		28	Syringes	28	DAYS				

PRIOR AUTHORIZATION 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 patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:
     1. The patient has a positive serological test for anti-AChR antibodies (lab test must be submitted) **AND**
     2. The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb **AND**
     3. The patient has a MG-Activities of Daily Living total score of greater than or equal to 6 **AND**
     4. ONE of the following:
        - A. The prescriber has assessed the patient's current medications and discontinued any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) **OR**
        - B. The prescriber has provided clinical rationale indicating that discontinuation of the offending agent is not clinically appropriate **AND**
     5. ONE of the following:
        - A. The patient's medication history includes at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) AND ONE of the following:
          1. The patient has had an inadequate response to a conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR**
          2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR**
        - B. The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR**
        - C. The patient has an FDA labeled contraindication to ALL of the following conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR**
        - D. The patient required chronic intravenous immunoglobulin (IVIG) **OR**
        - E. The patient required chronic plasmapheresis/plasma exchange **OR**
        - 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 ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) 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. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) 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 any of the following for the requested indication: A. Rystiggo (rozanolixizumab-noli) B. Soliris (eculizumab) C. Ultomiris (ravulizumab-cwvz) D. Vyvgart (efgartigimod) E. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The prescriber has provided information that the patient has had clinical benefit with the requested agent (e.g., improved MG-Activities of Daily Living total score, improved quantitative myasthenia gravis total score) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) 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 any of the following for the requested indication: A. Rystiggo (rozanolixizumab-noli) B. Soliris (eculizumab) C. Ultomiris (ravulizumab-cwvz) D. Vyvgart (efgartigimod) E. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **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) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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 3 months, Renewal 12 months

POLICIES REVISED

• Program Summary: Arikayce (amikacin liposome inhalation suspension)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
07000010121830	Arikayce	Amikacin Sulfate Liposome Inhal Susp 590 MG/8.4ML (Base Eq)	590 MG/8.4ML	28	Vials	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 *Mycobacterium avium* complex (MAC) lung disease as confirmed by BOTH of the following: A. Information has been provided that indicates the patient has at least ONE of the following clinical findings: pulmonary or systemic symptoms; nodular or cavitary opacities on chest radiograph; a high-resolution computed tomography scan that shows multifocal bronchiectasis with multiple small nodules **AND** B. Information has been provided that indicates the patient has at least ONE of the following microbiological findings: positive culture results from at least two separate expectorated sputum samples; positive culture result from at least one bronchial wash or lavage; transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or acid-fast bacilli [AFB]) AND positive culture for nontuberculous mycobacteria (NTM); biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) AND one or more sputum or bronchial washings that are culture positive for NTM **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	3. The patient has positive sputum cultures despite at least 6 consecutive months of treatment with guideline-based combination antibiotic therapy for MAC lung disease (e.g., standard combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 4. The patient will continue treatment with guideline-based combination antibiotic therapy for MAC lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) **OR** B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent **OR** 2. The prescriber has provided information in support of another inhaled antibiotic used concurrently with the requested agent **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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 continue treatment with guideline-based combination antibiotic therapy for *Mycobacterium avium* complex (MAC) lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following: A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) **OR** B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent **OR** 2. The prescriber has provided information in support of another inhaled antibiotic used concurrently with the requested agent **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
	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) exceeds 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: Baclofen

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
75100010001825	Fleqsuvy	Baclofen Susp	25 MG/5ML	480	mLs	30	DAYS				
75100010003010	Lyvispah	Baclofen Granules Packet	5 MG	120	Packets	30	DAYS				
75100010003020	Lyvispah	Baclofen Granules Packet	10 MG	120	Packets	30	DAYS				
75100010003030	Lyvispah	Baclofen Granules Packet	20 MG	120	Packets	30	DAYS				
75100010002070	Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	2400	mLs	30	DAYS				
75100010002075	Ozobax ds	baclofen oral soln	10 MG/5ML	1200	mLs	30	DAYS				

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. ALL of the following: A. The requested quantity (dose) exceeds 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:** Up to 12 months

• Program Summary: Cibinqo (abrocitinib)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90272005000320	Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000325	Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000330	Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS			09-01-2022	

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. 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** B. 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** C. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient's medication history includes at least a mid- potency topical steroid used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to mid- potency topical steroids used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over mid- potency topical steroids used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD 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. ONE of the following: A. The patient's medication history includes a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to a topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD 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. ONE of the following**:** A. The patient's medication history includes a systemic immunosuppressant, including a biologic AND ONE of the following: 1. The patient has had an inadequate response to a systemic immunosuppressant, including a biologic **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic immunosuppressant, including a biologic **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD 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** 5. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 6. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. 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 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 been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. 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** 6. 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:

Module	Clinical Criteria for Approval
	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 moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis 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., dermatologist, allergist, immunologist) 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**: 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) exceeds 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

CONTRAINDICATION AGENTS

Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
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)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Daybue (trofinetide)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Daybue 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of classic/typical Rett syndrome (RTT) **AND** 2. The patient has a disease-causing mutation in the MECP2 gene **AND** 2. If the patient has an FDA approved indication, then ONE of the following**:** A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient's weight is 9 kg or greater **AND** 4. The prescriber has assessed baseline status (prior to therapy with the requested agent) of the patient's RTT symptoms (e.g., speech patterns, hand movements, gait, growth, muscle tone, seizures, breathing patterns, quality of sleep **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., speech patterns, hand movements, gait, growth, muscle tone, seizures, breathing patterns, quality of sleep) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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: 3 months; Renewal: 12 months

• Program Summary: DPP-4 Inhibitors and Combinations

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502700340	Janumet	Sitagliptin-Metformin HCl Tab 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502700320	Janumet	Sitagliptin-Metformin HCl Tab 50-500 MG	50-500 MG	60	Tablets	30	DAYS				
27992502707540	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	30	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
27550070100340	Januvia	Sitagliptin Phosphate Tab 100 MG (Base Equiv)	100 MG	30	Tablets	30	DAYS				
27550070100320	Januvia	Sitagliptin Phosphate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550070100330	Januvia	Sitagliptin Phosphate Tab 50 MG (Base Equiv)	50 MG	30	Tablets	30	DAYS				
27992502400340	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502400320	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	60	Tablets	30	DAYS				
27992502400330	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502100330	Kazano	Alogliptin-Metformin HCl Tab 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				
27992502100320	Kazano	Alogliptin-Metformin HCl Tab 12.5-500 MG	12.5-500 MG	60	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
27550010100320	Nesina	Alogliptin Benzoate Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
27550010100330	Nesina	Alogliptin Benzoate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550010100310	Nesina	Alogliptin Benzoate Tab 6.25 MG (Base Equiv)	6.25 MG	30	Tablets	30	DAYS				
27550065100320	Onglyza	Saxagliptin HCl Tab 2.5 MG (Base Equiv)	2.5 MG	30	Tablets	30	DAYS				
27550065100330	Onglyza	Saxagliptin HCl Tab 5 MG (Base Equiv)	5 MG	30	Tablets	30	DAYS				
27994002100320	Oseni	Alogliptin-Pioglitazone Tab 12.5-15 MG	12.5-15 MG	30	Tablets	30	DAYS				
27994002100325	Oseni	Alogliptin-Pioglitazone Tab 12.5-30 MG	12.5-30 MG	30	Tablets	30	DAYS				
27994002100330	Oseni	Alogliptin-Pioglitazone Tab 12.5-45 MG	12.5-45 MG	30	Tablets	30	DAYS				
27994002100340	Oseni	Alogliptin-Pioglitazone Tab 25-15 MG	25-15 MG	30	Tablets	30	DAYS				
27994002100345	Oseni	Alogliptin-Pioglitazone Tab 25-30 MG	25-30 MG	30	Tablets	30	DAYS				
27994002100350	Oseni	Alogliptin-Pioglitazone Tab 25-45 MG	25-45 MG	30	Tablets	30	DAYS				
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS				
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS				
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS				
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Januvia** (sitagliptin) **Janumet** (sitagliptin/metformin) **Jentadueto** (linagliptin/metformin) **Kombiglyze XR** (saxagliptin/metformin ER) **Onglyza** (saxagliptin) **Tradjenta** (linagliptin) **Target Agent(s)** will be approved when ONE of the following is met: 1. Information has been provided that indicates the patient has been being treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 3. 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** 4. The patient's medication history includes use of an agent containing metformin or insulin **OR** 5. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: A. Insulin or an agent containing metformin 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 insulin or an agent containing metformin **OR** 6. The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following: metformin and insulins **OR** 8. The prescriber has provided documentation that metformin AND insulins 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 **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds 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**

Module	Clinical Criteria for Approval
	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) exceeds 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: Glucagon-like Peptide-1 (GLP-1) Agonists

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2717007000D220		Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)		2	Pens	28	DAYS				
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS				
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	2	Pens	180	DAYS				
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	4	Injection Devices	28	DAYS				
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS				
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	28	DAYS				
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS				
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS				
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS				
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS				
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS				
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS				
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML; 1.5 MG/0.5ML; 3 MG/0.5ML; 4.5 MG/0.5ML	4	Pens	28	DAYS				
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Bydureon BCise™** (exenatide extended-release) **Byetta®** (exenatide) **Ozempic®** (semaglutide) **Victoza®** (liraglutide) **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has a diagnosis of type 2 diabetes mellitus **AND** 2. ONE of the following: A. Information has been provided that indicates the patient is currently being treated with the requested GLP-1 within the past 90 days **OR** B. The prescriber states the patient is currently being treated with the requested GLP-1 within the past 90 days AND is at risk if therapy is changed **OR** 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 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** D. The patient's medication history includes use of one or more of the following: an agent containing metformin or insulin **OR** E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following:

Module	Clinical Criteria for Approval
	1. Insulin or an agent containing metformin 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 insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** G. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulin **OR** H. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** I. The prescriber has provided documentation that ALL of the following agents: metformin and insulin 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 **Length of Approval:** 12 months NOTE: If Quantity Limit program also 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 are 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: 1. BOTH of the following: A. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** B. 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** 3. BOTH of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● Program Summary: Growth Hormone

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

All products in this program are targeted, formulary and non-formulary. Additional FE review required for non-formulary drugs.

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ.

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; Ngenla; Norditropin flexpro; Nutropin aq nuspin 10; Nutropin aq nuspin 20; Nutropin aq nuspin 5; Omnitrope; Saizen; Saizenprep reconstitution; Serostim; Skytrofa; Sogroya; Zomacton; Zorbtive	lonapegsomatropin-tcgd for subcutaneous inj cart; lonapegsomatropin-tcgd for subcutaneous inj cartridge; somapacitan-beco solution pen-injector; somatrogon-ghla solution pen-injector; 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; somatropin for subcutaneous inj prefilled syr; somatropin solution cartridge; somatropin solution pen-injector	0.2 MG; 0.4 MG; 0.6 MG; 0.8 MG; 1 MG; 1.2 MG; 1.4 MG; 1.6 MG; 1.8 MG; 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; 24 MG/1.2ML; 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; 60 MG/1.2ML; 7.6 MG; 8.8 MG; 9.1 MG	M; N; O; Y				

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) Ngenla™ (somatrogon-ghla) Norditropin FlexPro® (somatropin) Nutropin AQ NuSpin® (somatropin) Saizen®, Saizenprep® (somatropin)

Module	Clinical Criteria for Approval

Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Sogroya® (somapacitan-beco)
Zomacton® (somatropin)
Zorbtive® (somatropin)

Adults – Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient is an adult (as defined by the prescriber) **AND**
2. 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/m^2 **OR**
                4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **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/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR**
                6. The patient's BMI is less than 20 kg/m^2 **AND**
            - B. All other causes of weight loss have been ruled out **OR**
    - B. If the request is for Zorbtive, then BOTH of the following:
        1. The patient has a diagnosis of short bowel syndrome (SBS) **AND**
        2. The patient is receiving specialized nutritional support **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**
        5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **OR**

Module	Clinical Criteria for Approval

D. The patient has another FDA approved indication for the requested agent and route of administration **OR**

E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

3. The request is for a long-acting GH agent AND if the patient has an FDA approved indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
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) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND**
7. ONE of the following:
   A. The request is for a preferred agent, 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

Compendia Allowed: CMS Approved Compendia

Length of Approval:

SBS	4 weeks
AIDS wasting/cachexia	12 weeks
Any other indication	12 months

Module	Clinical Criteria for Approval
	Adults – Renewal Evaluation **Target 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. The patient is an adult (as defined by the prescriber) **AND** 3. 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** 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** 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 growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone 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) **OR** D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
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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) is within FDA labeled dosing (or supported in compendia) for the requested indication AND
8. The patient is being monitored for adverse effects of GH

Compendia Allowed: CMS Approved Compendia

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>
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<tr><td>Child</td><td>
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)
Ngenla™ (somatrogon-ghla)
Norditropin FlexPro® (somatropin)
Nutropin AQ NuSpin® (somatropin)
Saizen®, Saizenprep® (somatropin)
Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Sogroya® (somapacitan-beco)
Zomacton® (somatropin)
Zorbtive® (somatropin)

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

Children – Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. The patient is a child (as defined by the prescriber) AND
2. 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:
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Module	Clinical Criteria for Approval
	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** 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**

Module	Clinical Criteria for Approval
	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** 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 growth hormone (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 **OR** M. The patient has another FDA approved indication for the requested agent and route of administration **OR** N. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. 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**

Module	Clinical Criteria for Approval
	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** 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) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications **Children – Renewal Evaluation** **Target 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. The patient is a child (as defined by the prescriber) **AND** 3. 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: 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**

Module	Clinical Criteria for Approval
	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** 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. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy **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 a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner Syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy **OR** D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR** E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **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) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications

● Program Summary: Insulin Combination Agents (Soliqua, Xultophy)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2799100235D220	Soliqua 100/33	Insulin Glargine-Lixisenatide Sol Pen-Inj 100-33 Unit-MCG/ML	100-33 UNIT-MCG/ML	6	Pens	30	DAYS				
2799100225D220	Xultophy 100/3.6	Insulin Degludec-Liraglutide Sol Pen-Inj 100-3.6 Unit-MG/ML	100-3.6 UNIT-MG/ML	5	Pens	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) exceeds 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) exceeds 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: Insulin Pumps

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
97201030506400	Omnipod 5 g6 intro kit (gen 5)	*insulin infusion disposable pump kit*		1	Kit	720	DAYS	08508300001			
97201030506300	Omnipod 5 g6 pods (gen 5); Omnipod classic pods (gen 5); Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies*		30	Pods	30	DAYS				
97201030506400	Omnipod classic pdm starter kit (gen 3)	*insulin infusion disposable pump kit*		1	Kit	720	DAYS	08508114002			
97201030506400	Omnipod dash intro kit (gen 4)	*insulin infusion disposable pump kit*		1	Kit	720	DAYS	08508200032			
97201030506400	Omnipod dash pdm kit (gen 4)	*insulin infusion disposable pump kit*		1	Kit	720	DAYS	08508200000			
97201030506410	Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24 HR	10	Kits	30	DAYS				
97201030506415	Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24 HR	10	Kits	30	DAYS				
97201030506420	Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24 HR	10	Kits	30	DAYS	08508400020			
97201030506425	Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24 HR	10	Kits	30	DAYS				
97201030506430	Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24 HR	10	Kits	30	DAYS	08508400030			
97201030506435	Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24 HR	10	Kits	30	DAYS				
97201030506440	Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24 HR	10	Kits	30	DAYS	08508400040			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Omnipod GO	**Omnipod GO** will be approved when BOTH of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been using the requested product within the past 90 days **OR** B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following:

Module	Clinical Criteria for Approval
	1. The patient has diabetes mellitus type 2 AND requires insulin therapy **AND** 2. The patient has completed a comprehensive diabetes education program **AND** 3. The patient has demonstrated willingness and ability to play an active role in diabetes self-management **AND** 2. ONE of the following: A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product **OR** B. The prescriber has provided information in support of using the requested product for the patient's age **Length of Approval:** 12 months
Omnipod, Omnipod 5 G6, Omnipod DASH	**Omnipod, Omnipod 5 G6, and Omnipod Dash** will be approved when BOTH of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been using the requested product within the past 90 days **OR** B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has diabetes mellitus AND requires insulin therapy **AND** 2. The patient is on an insulin regimen of 3 or more injections per day **AND** 3. The patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM) **AND** 4. The patient has completed a comprehensive diabetes education program **AND** 5. The patient has demonstrated willingness and ability to play an active role in diabetes self-management **AND** 6. The patient has had ONE of the following while compliant on an optimized multiple daily insulin injection regimen: A. Glycosylated hemoglobin level (HbA1C) greater than 7% **OR** B. History of recurring hypoglycemia **OR** C. Wide fluctuations in blood glucose before mealtime **OR** D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL **OR** E. History of severe glycemic excursions **AND** 2. ONE of the following: A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product **OR** B. The prescriber has provided information in support of using the requested product for the patient's age **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target agent(s)** will be approved for prescribed quantities 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: 1. The requested quantity (dose) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	2. Information has been provided in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Interleukin-4 (IL-4) Inhibitor

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14 ML	2	Pens	28	DAYS				
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS				
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67 ML	2	Syringes	28	DAYS				
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2	Syringes	28	DAYS				
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	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 moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR**

Module	Clinical Criteria for Approval
	B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient's medication history includes use of an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) OR BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) AND ONE of the following: 1. The patient has had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** 2. The patient has had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** 3. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) AND BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** C. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids, AND topical calcineurin inhibitors 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 prescriber has assessed the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The patient has eosinophilic type asthma AND ONE of the following: 1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has oral corticosteroid dependent type asthma **AND** 2. 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** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 3. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR** E. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient's medication history includes use of ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) AND ONE of the following: 1. The patient has had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** B. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy for EoE **OR** C. The patient has an FDA labeled contraindication to standard corticosteroid therapy for EoE **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL standard corticosteroid therapy for EoE 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** F. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: 1. The patient has ALL of the following features associated with PN: A. Presence of firm, nodular lesions **AND** B. Pruritus that has lasted for at least 6 weeks **AND** C. History and/or signs of repeated scratching, picking, or rubbing **AND** 2. ONE of the following: A. The patient's medication history includes use of at least a mid- potency topical steroid AND ONE of the following: 1. The patient has had an inadequate response to at least a mid- potency topical steroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least a mid- potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids 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** G. The patient has another FDA approved indication for the requested agent and route of administration **OR** H. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 3. If the patient has a diagnosis of moderate to severe asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. A leukotriene receptor antagonist (LTRA) **OR** C. Long-acting muscarinic antagonist (LAMA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a LABA, LTRA, LAMA, or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

Module	Clinical Criteria for Approval
	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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 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. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessnent (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of moderate to 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 (FEV_1) **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** 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, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR**

Module	Clinical Criteria for Approval
	D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyposis (CRSwNP) 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., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, 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
	Quantity Limits 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose, or the compendia supported 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 **Compendia Allowed:** CMS Approved Compendia **Length of Approval**: 6 months for Initial; 12 months for Renewal

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)

Contraindicated as Concomitant Therapy
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
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)

Contraindicated as Concomitant Therapy
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Kerendia

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30354030000310	Kerendia	Finerenone Tab	10 MG	30	Tablets	30	DAYS				
30354030000320	Kerendia	Finerenone Tab	20 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. 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** B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes and BOTH of the following: 1. ONE of the following: A. The patient will be using an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) (e.g., lisinopril, captopril) or an agent containing an angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan) at a maximally tolerated dose in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) AND an agent containing an angiotensin II receptor blocker (ARB) **OR** C. The patient has an FDA labeled contraindication to ALL agents containing an angiotensin-receptor enzyme inhibitor (ACEi) AND ALL agents containing an angiotensin II receptor blocker (ARB) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. BOTH of the following: 1. The patient's medication history includes an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) as indicated by ONE of the following: A. Evidence of a paid claim(s) within the past 999 days **OR** B. The prescriber has stated that the patient has tried an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) **AND** 2. ONE of the following: A. The agent containing an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) **OR** F. The prescriber has provided documentation that ALL agents containing an angiotensin-receptor enzyme inhibitor (ACEi) AND ALL agents containing an angiotensin II receptor blocker (ARB) 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. ONE of the following: A. The patient will be using an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) **OR** C. The patient has an FDA labeled contraindication to ALL agents containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) **OR** D. The patient has chronic kidney disease and is at increased risk for cardiovascular events or chronic kidney disease progression **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient's medication history includes an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease as indicated by ONE of the following: A. Evidence of a paid claim(s) within the past 999 days **OR** B. The prescriber has stated that the patient has tried an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease **AND** 2. ONE of the following: A. The agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease 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 the agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease **OR** G. The prescriber has provided documentation that ALL agents containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease 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** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient's serum potassium is less than or equal to 5.0 mEq/L **AND** 3. The patient's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2 **AND** 4. The patient's urine albumin-to-creatinine ratio (UACR) is greater than or equal to 30 mg/g **AND** 5. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 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**

Module	Clinical Criteria for Approval
	3. 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) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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: 4 months; Renewal: 12 months

• Program Summary: Opzelura (ruxolitinib)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90272060503720	Opzelura	Ruxolitinib Phosphate Cream	1.5 %	1	Tube	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<table><tr><th>Indication</th><th>PDL Preferred Agents</th></tr><tr><td>Atopic Dermatitis</td><td>Dupixent</td></tr></table> **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of mild to moderate atopic dermatitis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. The patient is NOT immunocompromised **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes at least a low-potency topical corticosteroid AND ONE of the following: 1. The patient has had an inadequate response to least a low-potency a topical corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical corticosteroid **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical corticosteroids 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. ONE of the following: A. The patient's medication history includes a topical calcineurin inhibitor AND ONE of the following: 1. The patient has had an inadequate response to a topical calcineurin inhibitor **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical calcineurin inhibitors **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical calcineurin inhibitor **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors 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** 5. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of nonsegmental vitiligo AND ALL of the following: 1. Vitiligo is NOT restricted from coverage under the patient's benefit **AND** 2. The patient's affected body surface area (BSA) is less than or equal to 10% **AND**

Module	Clinical Criteria for Approval
	3. ONE of the following: A. The patient has vitiligo impacting areas other than the face, neck, or groin AND ONE of the following: 1. The patient's medication history includes a potent topical corticosteroid AND ONE of the following: A. The patient has had an inadequate response to a potent topical corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL potent topical corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid for the treatment of vitiligo **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 ALL potent topical corticosteroids 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. The patient has vitiligo on the face, neck, or groin AND ONE of the following: 1. The patient's medication history includes a potent topical corticosteroid OR a topical calcineurin inhibitor AND ONE of the following: A. The patient has had an inadequate response to a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid OR a topical calcineurin inhibitor for the treatment of vitiligo **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**

Module	Clinical Criteria for Approval
	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 ALL potent topical corticosteroids AND topical calcineurin inhibitors 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. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) within the past 999 days **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) 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 the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. 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:

Module	Clinical Criteria for Approval
	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** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo 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) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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**: 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)

Contraindicated as Concomitant Therapy
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
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)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Rapid to Intermediate Acting Insulin

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27104005	Admelog; Admelog solostar; Humalog; Humalog junior kwikpen; Humalog kwikpen; Humalog tempo pen; Lyumjev; Lyumjev kwikpen; Lyumjev tempo pen	insulin lispro inj soln; insulin lispro soln cartridge; insulin lispro soln pen-inj w/transmitter port; insulin lispro soln pen-injector; insulin lispro-aabc inj; insulin lispro-aabc soln pen-inj; insulin lispro-aabc soln pen-inj w/transmit port; insulin lispro-aabc soln pen-injector	100 UNIT/ML; 200 UNIT/ML	45	mLs	30	DAYS				
27104005	Admelog; Admelog solostar; Humalog; Humalog junior kwikpen; Humalog kwikpen; Humalog tempo pen; Lyumjev; Lyumjev kwikpen; Lyumjev tempo pen	insulin lispro inj soln; insulin lispro soln cartridge; insulin lispro soln pen-inj w/transmitter port; insulin lispro soln pen-injector; insulin lispro-aabc inj; insulin lispro-aabc soln pen-inj; insulin lispro-aabc soln pen-inj w/transmit port; insulin lispro-aabc soln pen-injector	100 UNIT/ML; 200 UNIT/ML	45	mLs	30	DAYS				
27104004	Apidra; Apidra solostar	insulin glulisine inj; insulin glulisine soln pen-injector inj	100 UNIT/ML	45	mLs	30	DAYS				
27104002	Fiasp; Fiasp flextouch; Fiasp penfill; Fiasp pumpcart; Novolog; Novolog flexpen; Novolog flexpen relion; Novolog penfill; Novolog relion	insulin aspart (with niacinamide) inj; insulin aspart (with niacinamide) sol pen-inj; insulin aspart (with niacinamide) soln cartridge; insulin aspart inj soln; insulin aspart soln cartridge; insulin aspart soln pen-injector	100 UNIT/ML	45	mLs	30	DAYS				
27104080	Humalog mix 50/50; Humalog mix 50/50 kwikpen; Humalog mix 75/25; Humalog	insulin lispro prot & lispro inj; insulin lispro prot & lispro sus pen-inj; insulin lispro protamine & lispro inj	(50-50) 100 UNIT/ML; (75-25) 100 UNIT/ML	45	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
	mix 75/25 kwikpen										
27104090	Humulin 70/30; Humulin 70/30 kwikpen; Novolin 70/30; Novolin 70/30 flexpen; Novolin 70/30 flexpen relion; Novolin 70/30 relion	insulin nph & regular susp pen-inj; insulin nph isophane & regular human inj	(70-30) 100 UNIT/ML	45	mLs	30	DAYS				
27104020	Humulin n; Humulin n kwikpen; Novolin n; Novolin n flexpen; Novolin n flexpen relion; Novolin n relion	insulin nph (human) (isophane) inj; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	45	mLs	30	DAYS				
271040100020	Humulin r; Humulin r u-500 (concentr; Novolin r; Novolin r relion	insulin regular (human) inj	100 UNIT/ML; 500 UNIT/ML	45	mLs	30	DAYS				
2710401000D2	Humulin r u-500 kwikpen; Novolin r flexpen; Novolin r flexpen relion	insulin regular (human) soln pen-injector	100 UNIT/ML; 500 UNIT/ML	45	mLs	30	DAYS				
27104070	Novolog mix 70/30; Novolog mix 70/30 prefill; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj; insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	45	mLs	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds 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. There is support for 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**

Module	Clinical Criteria for Approval
	C. BOTH of the following: 1. The requested quantity (dose) exceeds 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: Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations

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

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Farxiga, Invokana, and Jardiance.

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27700010000320	Brenzavvy	bexagliflozin tab	20 MG	30	Tablets	30	DAYS				
277000402003	Farxiga	dapagliflozin propanediol tab	10 MG; 5 MG	30	Tablets	30	DAYS				
279965023003	Glyxambi	empagliflozin-linagliptin tab	10-5 MG; 25-5 MG	30	Tablets	30	DAYS				
40750010000320	Inpefa	sotagliflozin tab	200 MG	30	Tablets	30	DAYS				
40750010000340	Inpefa	sotagliflozin tab	400 MG	30	Tablets	30	DAYS				
279960022003	Invokamet	canagliflozin-metformin hcl tab	150-1000 MG; 150-500 MG; 50-1000 MG; 50-500 MG	60	Tablets	30	DAYS				
279960022075	Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG; 150-500 MG; 50-1000 MG; 50-500 MG	60	Tablets	30	DAYS				
277000200003	Invokana	canagliflozin tab	100 MG; 300 MG	30	Tablets	30	DAYS				
277000500003	Jardiance	empagliflozin tab	10 MG; 25 MG	30	Tablets	30	DAYS				
27996502200330	Qtern	Dapagliflozin-Saxagliptin Tab 10-5 MG	10-5 MG	30	Tablets	30	DAYS				
27996502200320	Qtern	Dapagliflozin-Saxagliptin Tab 5-5 MG	5-5 MG	30	Tablets	30	DAYS				
27996002450320	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27996002450310	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	120	Tablets	30	DAYS				
27996002450340	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-1000 MG	7.5-1000 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27996002450330	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-500 MG	7.5-500 MG	60	Tablets	30	DAYS				
27700055200340	Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 15 MG (Base Equiv)	15 MG	30	Tablets	30	DAYS				
27700055200320	Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS				
279965023503	Steglujan	ertugliflozin-sitagliptin tab	15-100 MG; 5-100 MG	30	Tablets	30	DAYS				
279960024003	Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG; 12.5-500 MG; 5-1000 MG; 5-500 MG	60	Tablets	30	DAYS				
27996002407540	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	60	Tablets	30	DAYS				
27996002407550	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				
27996002407560	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 25-1000 MG	25-1000 MG	30	Tablets	30	DAYS				
27996002407530	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS				
27996703407530	Trijardy xr	Empagliflozin-Linaglip-Metformin Tab ER 24HR 12.5-2.5-1000MG	12.5-2.5-1000 MG	60	Tablets	30	DAYS				
27996703407520	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 10-5-1000 MG	10-5-1000 MG	30	Tablets	30	DAYS				
27996703407540	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 25-5-1000 MG	25-5-1000 MG	30	Tablets	30	DAYS				
27996703407510	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab	5-2.5-1000 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		ER 24HR 5-2.5-1000MG									
27996002307525	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	30	Tablets	30	DAYS				
27996002307520	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-500 MG	10-500 MG	30	Tablets	30	DAYS				
27996002307507	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27996002307515	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS				
27996002307510	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
All other target agent(s)	**TARGET AGENT(S)** **Brenzavvy, Bexagliflozin** **Glyxambi** (empagliflozin/linagliptin) **Invokana** (canagliflozin) **Invokamet** (canagliflozin/metformin) **Invokamet XR** (canagliflozin/metformin ER) **Qtern** (dapagliflozin/saxagliptin) **Segluromet** (ertugliflozin/metformin) **Steglatro** (ertugliflozin) **Steglujan** (ertugliflozin/sitagliptin) **Synjardy** (empagliflozin/metformin) **Synjardy XR** (empagliflozin/metformin ER) **Trijardy XR** (empagliflozin/linagliptin/metformin ER) **Xigduo XR** (dapagliflozin/metformin ER) **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient's medication history includes use of an agent containing metformin or insulin **OR** 2. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: A. Insulin or an agent containing metformin 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 insulin or an agent containing metformin **OR** 3. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR**

Module	Clinical Criteria for Approval
	4. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **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 patient has an intolerance or hypersensitivity to one of the following agents: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulins **OR** 8. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 9. The prescriber has provided documentation that metformin AND insulin 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Farxiga	**TARGET AGENT(S)** **Farxiga** (dapagliflozin) **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient has a diagnosis of heart failure **OR** 2. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 3. The patient has a diagnosis of chronic kidney disease (CKD) **OR** 4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine 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 an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **OR** 8. 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** 9. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulins **OR**

Module	Clinical Criteria for Approval
	11. The prescriber has provided documentation that metformin AND insulin 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** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Jardiance and Inpefa	**TARGET AGENT(S)** **Jardiance** (empagliflozin) **Inpefa** (sotagliflozin) **Target Agent(s)** will be approved when ONE of the following is met: 1. If the requested agent is Jardiance, then BOTH of the following: A. The patient has a diagnosis of chronic kidney disease (CKD) **AND** B. The patient is at high risk for progression of CKD, including, risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization **OR** 2. The patient has a diagnosis of heart failure **OR** 3. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine 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 an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **OR** 8. 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**

Module	Clinical Criteria for Approval
	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** 9. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulin **OR** 11. The prescriber has provided documentation that metformin AND insulin 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** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine 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 **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. The requested quantity (dose) exceeds 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) exceeds 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: 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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82700040600120	Cerdelga	Eliglustat Tartrate Cap 84 MG (Base Equivalent)	84 MG	60	Capsules	30	DAYS				
30907760000120	Opfolda	miglustat (gaa deficiency) cap	65 MG	8	Capsules	28	DAYS				
82700070000120	Yargesa; Zavesca	Miglustat Cap 100 MG	100 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Cerdelga, Zavesca	**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** 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**

Module	Clinical Criteria for Approval

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.

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. 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**

Module	Clinical Criteria for Approval
	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.
Opfolda	**Initial Evaluation** **Opfolda** 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: 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** **Agents Eligible for Continuation of Therapy** Opfolda B. The patient has a diagnosis of late-onset Pompe disease (acid maltase deficiency [AMD]; glycogen storage disease type II [GSDII]) confirmed by at least ONE of the following: 1. Genetic analysis confirms biallelic mutation (two pathogenic variants) in the *GAA* gene **OR** 2. The patient has deficient acid alpha-glucosidase glycogen enzyme activity in dried blood spots, leukocytes, skin fibroblasts, and/or skeletal muscle tissue **AND** 2. The patient is not improving on their current enzyme replacement therapy (ERT) **AND**

Module	Clinical Criteria for Approval
	3. The requested agent will be taken in combination with Pombiliti **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The prescriber has assessed current status of the following: gross motor function (e.g., walking distance), pulmonary function (e.g., forced vital capacity [FVC]) **AND** 6. 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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Opfolda** 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. Gross motor function (e.g., walking distance) **OR** B. Pulmonary function (e.g., forced vital capacity [FVC]) **AND** 3. 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** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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: Sunosi (solriamfetol)

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61370070200340	Sunosi	Solriamfetol HCl Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND ALL of the following: 1. The underlying airway obstruction has been treated (e.g., continuous positive airway pressure [CPAP]) for at least 1-month prior to initiating therapy with the requested agent **AND** 2. The modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 3. ONE of the following: A. The patient's medication history armodafinil OR modafinil AND ONE of the following: 1. The patient has had an inadequate response to armodafinil OR modafinil **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND modafinil **OR** B. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** C. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH armodafinil AND modafinil 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. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND ONE of the following: 1. The patient's medication history armodafinil OR modafinil AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has had an inadequate response to armodafinil OR modafinil **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND modafinil **OR** 2. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **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 the 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 BOTH armodafinil AND modafinil 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. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **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. If the diagnosis is excessive daytime sleepiness associated with obstructive sleep apnea (OSA), the modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) 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

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) exceeds 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: 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	Targeted NDCs When Exclusions Exist	Age Limit	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. BOTH of the following: 1. The patient has a diagnosis of severe asthma **AND** 2. 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** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**

Module	Clinical Criteria for Approval
	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 a diagnosis of severe asthma, ALL of the following: A. ONE of the following: 1. 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** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated for at least 3 months with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. A leukotriene receptor antagonist (LTRA) **OR** C. Long-acting muscarinic antagonist (LAMA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 3. 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** 4. 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** 5. 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** 6. 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.

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. 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** 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
	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) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)

Contraindicated as Concomitant Therapy
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
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)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

● Program Summary: Thrombopoietin Receptor Agonists and Tavalisse

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

Nplate is not a target in this program.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82405030050310	Alvaiz	eltrombopag choline tab	9 MG	30	Tablets	30	DAYS				
82405030050320	Alvaiz	eltrombopag choline tab	18 MG	30	Tablets	30	DAYS				
82405030050330	Alvaiz	eltrombopag choline tab	36 MG	60	Tablets	30	DAYS				
82405030050340	Alvaiz	eltrombopag choline tab	54 MG	60	Tablets	30	DAYS				
82405010200320	Doptelet	Avatrombopag Maleate Tab 20 MG (Base Equiv)	20 MG	60	Tablets	30	DAYS				
82405045000320	Mulpleta	Lusutrombopag Tab 3 MG	3 MG	7	Tablets	7	DAYS				
82405030103030	Promacta	Eltrombopag Olamine Powder Pack for Susp 12.5 MG (Base Eq)	12.5 MG	30	Packets	30	DAYS				
82405030103020	Promacta	Eltrombopag Olamine Powder Pack for Susp 25 MG (Base Equiv)	25 MG	30	Packets	30	DAYS				
82405030100310	Promacta	Eltrombopag Olamine Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
82405030100320	Promacta	Eltrombopag Olamine Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
82405030100330	Promacta	Eltrombopag Olamine Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS				
82405030100340	Promacta	Eltrombopag Olamine Tab 75 MG (Base Equiv)	75 MG	60	Tablets	30	DAYS				
857560401003	Tavalisse	fostamatinib disodium tab	100 MG; 150 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The requested agent is Doptelet AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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** I. The prescriber has provided documentation that corticosteroids 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. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 3. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** C. The patient has another FDA approved indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	D. The patient has another indication supported in compendia for the requested agent **OR** 2. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: A. BOTH of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND BOTH of the following: A. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** B. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** B. The patient has another FDA approved indication for the requested agent **OR** C. The patient has another indication supported in compendia for the requested agent **OR** 3. The requested agent is Nplate (romiplostim) AND ONE of the following: A. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** B. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following: 1. ONE of the following: A. The patient is between the ages of 1 and 17 years old AND the diagnosis has lasted for at least 6 months **OR** B. The patient is 18 years old or over **AND** 2. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** 3. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **OR** G. 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**

Module	Clinical Criteria for Approval
	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** H. The prescriber has provided documentation that corticosteroids 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. The patient has another FDA approved indication for the requested agent **OR** D. The patient has another indication supported in compendia for the requested agent **OR** 4. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following: A. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: 1. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate pegylated interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR** 2. The patient is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** B. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: 1. The patient has at least 2 of the following blood criteria: A. Neutrophils less than 0.5 X 10^9/L B. Platelets less than 30 X 10^9/L C. Reticulocyte count less than 60 X 10^9/L **AND** 2. The patient has 1 of the following marrow criteria: A. Severe hypocellularity: less than 25% **OR** B. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient will use the requested agent as first-line treatment **AND** 2. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** B. ONE of the following: 1. The patient's medication history includes BOTH antithymocyte globulin (ATG) AND cyclosporine therapy AND ONE of the following: A. The patient has had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** 2. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR**

Module	Clinical Criteria for Approval
	3. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **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 BOTH antithymocyte globulin (ATG) AND cyclosporine therapy 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. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** B. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **OR** G. 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**

Module	Clinical Criteria for Approval
	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** H. The prescriber has provided documentation that corticosteroids 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** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication supported in compendia for the requested agent **OR** 5. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following; A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** I. The prescriber has provided documentation that corticosteroids 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. The patient has another FDA approved indication for the requested agent **OR** C. The patient has another indication supported in compendia for the requested agent **AND** B. If the patient has an FDA approved indication, 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 **AND** C. ONE of the following: 1. The patient will NOT use the requested agent in combination with another agent included in this program **OR** 2. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: A. The requested agent is Nplate **AND** B. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND** D. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **Initial Lengths of Approval:** **Doptelet:** **ITP:** 6 months **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Mulpleta** **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Nplate** **HS-ARS:** 1 time **ITP:** 4 months **All other indications:** 6 months **Promacta** **ITP:** 2 months **Thrombocytopenia in Hep C:** 3 months **First-Line therapy in severe aplastic anemia:** 6 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months

Module	Clinical Criteria for Approval
	Alvaiz **ITP:** 2 months **Thrombocytopenia in hep C:** 3 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months **Tavalisse** **All indications:** 6 months NOTE if Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process. Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: 1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR** 2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR** B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following: 1. ONE of the following: A. The patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin **OR** B. The patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin **AND** 2. ONE of the following: A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR** B. The patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C **OR** C. The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency) **AND** 2. The patient will NOT use the requested agent in combination with another agent included in this program **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **Renewal Lengths of approval:** **ITP**:12 months **Thrombocytopenia in hepatitis C:** 6 months **All other indications for the requested agent:** 12 months

Module	Clinical Criteria for Approval
	NOTE if Quantity Limit Applies, please see 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 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 **Initial Lengths of Approval:** **Doptelet:** **ITP:** 6 months **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Mulpleta:** **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Nplate** **HS-ARS:** 1 time **ITP:** 4 months **All other indications:** 6 months **Promacta** **ITP:** 2 months **Thrombocytopenia in Hep C:** 3 months **First-Line therapy in severe aplastic anemia:** 6 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months **Alvaiz** **ITP:** 2 months **Thrombocytopenia in hep C:** 3 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months

Module	Clinical Criteria for Approval
	Tavalisse **All indications:** 6 months **Renewal Lengths of approval:** **ITP:** 12 months **Severe aplastic anemia:** 12 months **All other indications for the requested agent:** 12 months **Thrombocytopenia in hepatitis C:** 6 months

● Program Summary: Vascepa

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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39500035100110	Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	240	Capsules	30	DAYS			07-01-2019	
39500035100120	Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	120	Capsules	30	DAYS			07-01-2019	

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 patient has a pre-treatment triglyceride (TG) level of greater than or equal to 500 mg/dL **OR** B. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following: 1. ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **AND** 2. The patient's triglyceride (TG) level is greater than or equal to 135 mg/dL **AND** 3. ONE of the following: A. The patient has established cardiovascular disease **OR** B. The patient has diabetes mellitus AND 2 or more additional risk factors for cardiovascular disease (e.g., hypertension, premature family history, chronic kidney disease) **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 approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: CMS approved compendia **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 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) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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: Zeposia

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

For MN Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug for Ulcerative Colitis: Humira and Xeljanz

For MN Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs for Multiple Sclerosis: Aubagio, Avonex, Avonex pen, Betaseron kit, Betaseron vial, Copaxone 20 mg/mL, Dimethyl fumarate DR, Gilenya, Rebif, and Rebif Rebidose pen.

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62407050200120	Zeposia	Ozanimod HCl Cap 0.92 MG	0.92 MG	30	Capsule	30	DAYS				
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG	4 x 0.23MG & 3 x 0.46MG	7	Capsules	180	DAYS				
6240705020B215	Zeposia starter kit	ozanimod cap pack	0.23MG &0.46MG 0.92MG(21)	28	Capsules	180	DAYS				
6240705020B220	Zeposia starter kit	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG & 30 x 0.92 MG	0.23MG & 0.46MG & 0.92MG	37	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred	**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**: Zeposia (ozanimod) 1. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a relapsing form of multiple sclerosis (MS) AND ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of clinically isolated syndrome (CIS) and ALL of the following: 1. The patient had a single event that lasted at least 24 hours **AND** 2. The event was not due to fever or infection **AND** 3. The patient has multiple sclerosis (MS)-like brain lesion(s) confirmed by magnetic resonance imaging (MRI) **OR**

Module	Clinical Criteria for Approval
	B. The patient has a diagnosis of relapsing remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS) **AND** 2. ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) 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 the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) used for the requested indication (Please refer to "MS DMA Agents" contraindicated table) **OR** B. The patient will be using the requested agent in combination with another DMA used for the treatment of MS AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad (cladribine) **AND** 2. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad (cladribine) **OR** C. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following: 1. ONE of the following: A. 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**

Module	Clinical Criteria for Approval
	B. The patient's medication history includes ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC AND ONE of the following: 1. The patient has had an inadequate response to a conventional agent used in the treatment of UC **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of UC **OR** C. The patient has severely active ulcerative colitis **OR** D. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** E. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** F. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** G. The prescriber has provided documentation that ALL of the conventional agents used in the treatment of UC 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. ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to Humira or Xeljanz is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to Humira or Xeljanz as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried Humira or Xeljanz **AND** 2. ONE of the following: A. Humira or Xeljanz were 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 Humira or Xeljanz **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Humira AND Xeljanz that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that Humira AND Xeljanz 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** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over Humira AND Xeljanz **OR** F. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in Compendia for the treatment of UC **AND** 3. ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table):

Module	Clinical Criteria for Approval
	A. The patient will NOT be using the requested agent in combination with an immunomodulatory (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with an 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 the combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 2. The prescriber has performed an electrocardiogram within 6 months prior to initiating treatment **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months. **Compendia Allowed:** CMS Approved Compendia 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., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient has a diagnosis of multiple sclerosis AND ONE of the following: 1. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) for the requested indication (Please refer to "MS DMA Agents" contraindicated use table **OR** 2. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following: A. The requested agent will be used in combination with Mavenclad (cladribine) **AND** B. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **OR** B. The patient has a diagnosis of ulcerative colitis AND ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table: 1. The patient will NOT be using the requested agent in combination with an immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

Module	Clinical Criteria for Approval
	A. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** B. 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 **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
Zeposia PA through preferred and Zeposia PA with MS step	**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) exceeds 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds 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. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CLASS AGENTS

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: CD 52 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD 52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug classes: Fumarates	
MS Disease Modifying Agents drug classes: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: Glatiramer	
MS Disease Modifying Agents drug classes: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug classes: Interferons	
MS Disease Modifying Agents drug classes: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	REBIF*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: MS Disease Modifying Agents drug classes	
MS Disease Modifying Agents drug classes: MS Disease Modifying Agents drug classes	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug classes: Purine antimetabolite	
MS Disease Modifying Agents drug classes: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)

Contraindicated as Concomitant Therapy
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)
dimethyl fumarate
Extavia (interferon b-1b)
fingolimod
Gilenya (fingolimod)
Glatopa (glatiramer)
glatiramer
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)
Plegridy (peginterferon b-1a)
Ponvory (ponesimod)
Rebif (interferon b-1a)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)
Vumerity (diroximel fumarate)
Zeposia (ozanimod)
Immunomodulatory Agents NOT to be used concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)

Contraindicated as Concomitant Therapy
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
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)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)