MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: May 1, 2024 Notification Posted: April 17, 2024

BlueCross BlueShield Minnesota

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NEW POLICIES DEVELOPED

No new policies for May 1, 2024

POLICIES REVISED

• Program Summary: Afrezza (regular human insulin, inhaled)

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
27104010002990	Afrezza	Insulin Regular (Human) Inh Powd 4 & 8 & 12 Unit/Cart (60)	60x4 & 60x8 & 60x12 UNIT	1260	Cartridges	30	DAYS				
27104010002988	Afrezza	Insulin Regular (Human) Inh Powd 90 x 8 Unit & 90 x 12 Unit	90x8 UNIT & 90x12 UNIT	1080	Cartridges	30	DAYS				
27104010002978	Afrezza	Insulin Regular (Human) Inhal Powd 90 x 4 Unit & 90 x 8 Unit	90x4 UNIT & 90x8 UNIT	1800	Cartridges	30	DAYS				
27104010002955	Afrezza	Insulin Regular (Human) Inhalation Powder 12 Unit/Cartridge	12 UNIT	900	Cartridges	30	DAYS				
27104010002940	Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	2520	Cartridges	30	DAYS				
27104010002950	Afrezza	Insulin Regular (Human) Inhalation Powder 8 Unit/Cartridge	8 UNIT	1260	Cartridges	30	DAYS				

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 **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: Interleukin-5 (IL-5) Inhibitors

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
4460402000D520	Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	1	Pen	56	DAYS				
4460405500E520	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4ML	1	Syringe	28	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
4460405500D530	Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML	Severe eosinophilic asthma and CRSwNP: 1 syringe/28 days. EGPA and HES: 3 syringes/28 days.			
4460405500E530	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe 100 MG/ML	100 MG/ML	Severe eosinophilic asthma and CRSwNP: 1 syringe/28 days. EGPA and HES: 3 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 patient has a diagnosis of severe eosinophilic asthma and ALL of the following: 1. The patient's diagnosis has been confirmed by ONE of the following: A. 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** B. 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** C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **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**

Module	Clinical Criteria for Approval
	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 **AND** 3. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 4. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** 5. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 6. If the requested agent is Nucala, then ONE of the following: A. The patient's medication history includes use of Fasenra AND ONE of the following: 1. The patient has had an inadequate response to Fasenra **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Fasenra **OR** B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Fasenra **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 prescriber has provided documentation that Fasenra 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 eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:

Module	Clinical Criteria for Approval
	1. The requested agent is Nucala **AND** 2. The patient has had a diagnosis of EGPA for at least 6 months with a history of relapsing or refractory disease **AND** 3. The patient's diagnosis of EGPA was confirmed by ONE of the following: A. The patient meets 4 of the following: 1. Asthma (history of wheezing or diffuse high-pitched rales on expiration) 2. Eosinophilia (greater than 10% eosinophils on white blood cell differential count) 3. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis 4. Migratory or transient pulmonary infiltrates detected radiographically 5. Paranasal sinus abnormality 6. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas **OR** B. The patient meets ALL of the following: 1. Medical history of asthma **AND** 2. Peak peripheral blood eosinophilia greater than 1500 cells/microliter **AND** 3. Systemic vasculitis involving two or more extra-pulmonary organs **AND** 4. ONE of the following: A. The patient is currently on maximally tolerated oral corticosteroid therapy **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral 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 oral 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** 5. ONE of the following: A. The patient's medication history includes use of an non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) AND ONE of the following: 1. The patient has had an inadequate response to ONE non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, rituximab) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over non-corticosteroid immunosuppressant therapy **OR** B. The patient has an intolerance or hypersensitivity to ONE non-corticosteroid immunosuppressant therapy **OR** C. The patient has an FDA labeled contraindication to ALL of the following immunosuppressants: 1. Azathioprine

Module	Clinical Criteria for Approval
	2. Cyclophosphamide 3. Methotrexate 4. Mycophenolate mofetil **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 azathioprine, cyclophosphamide, methotrexate, AND mycophenolate mofetil 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 hypereosinophilic syndrome (HES) and ALL of the following: 1. The requested agent is Nucala **AND** 2. BOTH of the following: A. The patient has had a diagnosis of HES for at least 6 months **AND** B. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **AND** 3. The patient's diagnosis of HES was confirmed by BOTH of the following: A. ONE of the following: 1. The patient has a peripheral blood eosinophil count greater than 1000 cells/microliter **OR** 2. The patient has a percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells **OR** 3. The patient has marked deposition of eosinophil granule proteins found **OR** 4. The patient has tissue infiltration by eosinophils that is extensive in the opinion of a pathologist **AND** B. ALL of the following: 1. Secondary (reactive, non-hematologic) causes of eosinophilia have been excluded (e.g., infection, allergy/atopy, medications, collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma) **AND** 2. There has been evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) **AND** 3. The patient does NOT have *FIP1L1-PDGFRA*-positive disease **AND** 4. ONE of the following: A. The patient is currently being treated with maximally tolerated oral corticosteroid (OCS) **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid (OCS) therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **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 oral 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** 5. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. Hydroxyurea **OR** 2. Interferon-α **OR** 3. Another immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with hydroxyurea, interferon-α, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **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 hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-α, immunosuppressants) in combination with the requested agent **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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** 3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 4. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR**

Module	Clinical Criteria for Approval
	B. Computed tomography (CT) of the sinuses **AND** 5. 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** 6. 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 **AND** 7. 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 **OR** E. The patient has another FDA approved indication for the requested agent and route of administration **OR** F. 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved indications

Module	Clinical Criteria for Approval
	For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of severe eosinophilic 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. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. 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], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **OR** B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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. Remission achieved with the requested agent **OR** B. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR** C. Decrease in hospitalization due to symptoms of EGPA **OR** D. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral 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 oral 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

Module	Clinical Criteria for Approval
	maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of hypereosinophilic syndrome (HES) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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. Decrease in incidence of HES flares **OR** B. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has not been required **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with oral corticosteroid and/or other maintenance therapy (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with oral corticosteroids or other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **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 oral corticosteroids and other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) 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 a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. 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** F. 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, otolaryngologist, 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:

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** 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 for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved indications; For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 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)

Contraindicated as Concomitant Therapy
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: Long 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
2710400300D220	Basaglar kwikpen; Lantus solostar; Semglee	Insulin Glargine Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
2710400300D222	Basaglar tempo pen	Insulin Glargine Pen-Inj with Transmitter Port	100 UNIT/ML	45	mLs	30	DAYS				
27104003002020	Lantus; Semglee	Insulin Glargine Inj 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
27104006002020	Levemir	Insulin Detemir Inj 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
2710400600D220	Levemir flexpen; Levemir flextouch	Insulin Detemir Soln Pen-injector 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
2710400305D220	Rezvoglar kwikpen	insulin glargine-aglr soln pen-injector	100 UNIT/ML	45	mLs	30	DAYS				
27104003902020	Semglee	Insulin Glargine-yfgn Inj	100 UNIT/ML	45	mLs	30	DAYS				
2710400390D220	Semglee	Insulin Glargine-yfgn Soln Pen-Injector	100 UNIT/ML	45	mLs	30	DAYS				
2710400300D236	Toujeo max solostar	Insulin Glargine Soln Pen-Injector 300 Unit/ML (2 Unit Dial)	300 UNIT/ML	45	mLs	30	DAYS				
2710400300D233	Toujeo solostar	Insulin Glargine Soln Pen-Injector 300 Unit/ML (1 Unit Dial)	300 UNIT/ML	45	mLs	30	DAYS				
27104007002020	Tresiba	Insulin Degludec Inj 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
2710400700D210	Tresiba flextouch	Insulin Degludec Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	45	mLs	30	DAYS				
2710400700D220	Tresiba flextouch	Insulin Degludec Soln Pen-Injector 200 Unit/ML	200 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:

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27250050007520		metformin HCl Tab ER 24HR 500 MG	500 MG	120	Tablets	30	DAYS				
27250050007530		metformin HCl Tab ER 24HR 750 MG	750 MG	60	Tablets	30	DAYS				
27250050007570		metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	60	Tablets	30	DAYS				
27250050007560		metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	90	Tablets	30	DAYS				
27250050007590	Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	60	Tablets	30	DAYS				
27250050007580	Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	90	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Avonex, Avonex pen, Betaseron kit, Betaseron vial, Copaxone 20 mg/mL, Dimethyl fumarate, fingolimod, Rebif, Rebif Rebidose pen, and teriflunomide tablet.

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
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F8	Avonex	interferon beta-	30 MCG/0.5 ML	4	Syringes	28	DAYS				
6240306045F5	Avonex pen	interferon beta-	30 MCG/0.5 ML	4	Pens	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
624030605064	Betaseron	Interferon Beta-; interferon beta-	0.3 MG	14	Vials	28	DAYS	50419052401; 50419052435			
6240003010E520	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS				
6240003010E540	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS				
624030605064	Extavia	Interferon Beta- ; interferon beta-	0.3 MG	15	Vials	30	DAYS	00078056912; 00078056961; 00078056999			
624070251001	Gilenya	fingolimod hcl cap	0.25 MG; 0.5 MG	30	Capsules	30	DAYS				
6240506500D520	Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4 ML	1	Syringe	28	DAYS				
6240101500B744	Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	DAYS				
6240101500B718	Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	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
6240101500B722	Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS				
6240101500B726	Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS				
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	7	Tablets	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	12	Tablets	180	DAYS				
6240307530E521	Plegridy	Peginterferon Beta-	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D220	Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5 ML	2	Pens	28	DAYS				
6240307530E520	Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D250	Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
6240307530E550	Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
62407060000320	Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS				
6240706000B720	Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	14	Tablets	180	DAYS				
6240306045E520	Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045E540	Rebif	Interferon Beta-1a Soln Pref Syr 44	44 MCG/0.5 ML	12	Syringes	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
		MCG/0.5ML (24MU/ML)									
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D540	Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D560	Rebif titration pack	Interferon Beta-1a Auto-Inj 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
624070252072	Tascenso odt	fingolimod lauryl sulfate tablet disintegrating	0.25 MG; 0.5 MG	30	Tablets	30	DAYS				
62405525006520	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsules	180	DAYS				
62405525006540	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsules	30	DAYS				
6240552500B320	Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS				
62405530006540	Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Mavenclad	**TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs** **Preferred Agents** **Avonex®** (interferon beta-1a) **Betaseron®** (interferon beta-1b) **Copaxone®** 20 mg/mL (glatiramer)* **dimethyl fumarate** **fingolimod** **Rebif®** (interferon beta-1a) **teriflunomide** **Nonpreferred Agents** **Aubagio®** (teriflunomide)* **Bafiertam™** (monomethyl fumarate) **Copaxone®** 40 mg/mL (glatiramer)* **dimethyl fumarate Starter Pack** **Extavia®** (interferon beta-1b)Glatiramer 20 mg/mL **Gilenya®** (fingolimod)*

Module	Clinical Criteria for Approval

Glatiramer 40 mg/mL
Glatopa® (glatiramer)*
Kesimpta® (ofatumumab)
Mavenclad® (cladribine)
Mayzent® (siponimod)
Plegridy® (peginterferon beta-1a)
Ponvory™ (ponesimod)
Tecfidera® (dimethyl fumarate)*
Tascenso ODT™ (fingolimod)
Vumerity® (diroximel fumarate)
* -generic available

FDA Approved Indication	FDA Approved Agent(s)
Clinically Isolated Syndrome (CIS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Relapsing Remitting Multiple Sclerosis (RRMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Active Secondary Progressive Multiple Sclerosis (SPMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity

Initial Evaluation

Mavenclad (cladribine) will be approved when ALL of the following are met:
1. ONE of the following:
    A. Information has been provided that the patient has been treated with the requested agent 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 the patient is at risk if therapy is changed **OR**
    C. The patient has ONE of the following relapsing forms of multiple sclerosis (MS):
        1. Relapsing-remitting disease (RRMS)
        2. Active secondary progressive disease (SPMS) **AND**
2. ONE of the following:
    A. 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 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**
        2. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** 3. The patient has an intolerance or hypersensitivity to two 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** 4. The patient has an FDA labeled contraindication to ALL 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** 5. The prescriber has provided information that the required 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** 6. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **OR** B. The patient has been previously treated with the requested agent AND BOTH of the following: 1. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND** 2. The patient has NOT completed 2 courses of the requested agent (one course consists of 2 cycles of 4-5 days each) **AND** 3. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The lymphocyte count is within normal limits **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) 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 will NOT be using the requested agent with an additional disease modifying agent (DMA) for the requested indication **OR** B. BOTH of the following: 1. The patient is currently using the requested agent **AND** 2. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles) **AND** 7. 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** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The requested quantity (dose) does not exceed the FDA labeled maximum dose based on the patient's weight **Length of Approval:** 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days) NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Mavenclad (cladribine)** 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. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The patient has a lymphocyte count of at least 800 cells/µL **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) 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 will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. It has been at least 35 weeks but not more than 67 weeks since the last dose of the requested agent **AND** 9. BOTH of the following: A. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND** B. The patient has NOT completed 2 courses with the requested agent (one course consists of 2 cycles of 4-5 days) **AND** 10. The requested quantity (dose) does not exceed the FDA labeled maximum dose based on the patient's weight **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria
MS Agents other than Mavenclad	**TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs** **Preferred Agents** **Avonex®** (interferon beta-1a) **Betaseron®** (interferon beta-1b) **Copaxone®** 20 mg/mL (glatiramer)* **dimethyl fumarate** **fingolimod** **Rebif®** (interferon beta-1a) **teriflunomide** **Nonpreferred Agents** **Aubagio®** (teriflunomide) **Bafiertam™** (monomethyl fumarate) **Copaxone®** 40 mg/mL (glatiramer)* **dimethyl fumarate Starter Pack** **Extavia®** (interferon beta-1b) **Glatiramer 20 mg/mL** **Gilenya®** (fingolimod)* **Glatiramer 40 mg/mL** **Glatopa®** (glatiramer)* **Kesimpta®** (ofatumumab) **Mavenclad®** (cladribine) **Mayzent®** (siponimod) **Plegridy®** (peginterferon beta-1a) **Ponvory™** (ponesimod) **Tecfidera®** (dimethyl fumarate)* **Tascenso ODT™** (fingolimod) **Vumerity®** (diroximel fumarate) * -generic available

Module	Clinical Criteria for Approval

FDA Approved Indication	FDA Approved Agent(s)
Clinically Isolated Syndrome (CIS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Relapsing Remitting Multiple Sclerosis (RRMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Active Secondary Progressive Multiple Sclerosis (SPMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity

Initial Evaluation

Target Agent(s) (excluding Mavenclad [cladribine]) will be approved when ALL of the following are met:

1. ONE of the following:
    - A. Information has been provided that the patient has been treated with the requested agent 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 a relapsing form of 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 MS-like brain lesion(s) confirmed by magnetic resonance imaging (MRI) **OR**
            - B. The patient has a diagnosis of relapsing remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS) **AND**
        2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and 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**
            - B. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:
                1. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** C. The patient has an intolerance or hypersensitivity to two 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 patient has an FDA labeled contraindication to ALL 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** E. The prescriber has provided information that the required 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** F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **AND** 3. If the requested agent is Aubagio (teriflunomide), the prescriber has obtained transaminase and bilirubin levels within 6 months prior to initiating treatment **AND** 4. If the requested agent is Gilenya (fingolimod) or Tascenso ODT (fingolimod) the prescriber has performed an electrocardiogram within 6 months prior to initiating treatment **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. 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: 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) **AND** 4. 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:** For agents requiring a starter dose for initial use, 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. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target agent(s) (excluding Mavenclad [cladribine])** 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 (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	4. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. The patient will be using the requested agent in combination with another DMA used for the requested indication 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) **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
QL with PA - All agents excluding Mavenclad	**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**: For agents requiring a starter dose for initial use, 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.
QL with PA Mavenclad	**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) cannot be achieved with a lower quantity of packs and a higher pack size (e.g., two 10 tablet packs instead of four 5 tablet packs) that does not exceed the program quantity limit **Length of Approval:** Initial: 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days); Renewal: 3 months

CLASS AGENTS

Class	Class Drug Agents
Class Ia antiarrhythmics	
Class Ia antiarrhythmics	NORPACE*Disopyramide Phosphate Cap
Class Ia antiarrhythmics	Pronestyl (procainamide)
Class Ia antiarrhythmics	quinidine
Class III antiarrhythmics	
Class III antiarrhythmics	BETAPACE*Sotalol HCl Tab
Class III antiarrhythmics	Cordarone, Pacerone (amiodarone)
Class III antiarrhythmics	CORVERT*Ibutilide Fumarate Inj
Class III antiarrhythmics	MULTAQ*Dronedarone HCl Tab
Class III antiarrhythmics	TIKOSYN*Dofetilide Cap
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug class: Fumarates	
MS Disease Modifying Agents drug class: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Glatiramer	
MS Disease Modifying Agents drug class: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug class: Interferons	
MS Disease Modifying Agents drug class: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	EXTAVIA*Interferon beta-1b injection

Class	Class Drug Agents
MS Disease Modifying Agents drug class: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	REBIF*Interferon Beta-
MS Disease Modifying Agents drug class: Purine antimetabolite	
MS Disease Modifying Agents drug class: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs) **Aubagio** (teriflunomide)* **Avonex** (interferon β-1a) **Bafiertam** (monomethyl fumarate) **Betaseron** (interferon β-1b) **Briumvi** (ublituximab-xiiy) **Copaxone** (glatiramer)* dimethyl fumarate **Extavia** (interferon β-1b) fingolimod **Gilenya** (fingolimod)* **Glatopa** (glatiramer) glatiramer **Kesimpta** (ofatumumab) **Lemtrada** (alemtuzumab) **Mavenclad** (cladribine) **Mayzent** (siponimod)

Contraindicated as Concomitant Therapy
Ocrevus (ocrelizumab) **Plegridy** (peginterferon β-1a) **Ponvory** (ponesimod) **Rebif** (interferon β-1a) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)* teriflunomide **Tysabri** (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

● Program Summary: Rezurock (belumosudil)

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
99398510500320	Rezurock	Belumosudil Mesylate Tab	200 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 requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Rezurock 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 chronic graft-versus-host disease (chronic GVHD) **AND** 2. ONE of the following: A. The patient's medication history includes therapy with at least two prior lines of systemic therapy AND ONE of the following: 1. The patient has had an inadequate response to at least two prior lines of systemic therapy **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 two prior lines of systemic therapy **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least two prior lines of systemic therapy **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL lines of systemic therapy **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 systemic 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 **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., hematologist, oncologist) or 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 therapy with 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 Review 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., hematologist, oncologist) or 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**

Module	Clinical Criteria for Approval
	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 for the requested indication **Length of Approval:** 12 months

• Program Summary: Risdiplam

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
74706560002120	Evrysdi	Risdiplam For Soln	0.75 MG/ML	240	mLs	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. The patient has a diagnosis of Spinal Muscular Atrophy (SMA) type 1, 2, or 3 **AND** B. The patient's diagnosis was confirmed by genetic testing confirming the mutation or deletion of genes in chromosome 5q (medical records required) **AND** C. The patient has had at least ONE of the following baseline (prior to starting therapy with the requested agent) functional assessments based on patient age and motor ability: 1. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) 2. Hammersmith Infant Neurological Examination (HINE-2) 3. Hammersmith Functional Motor Scale-Expanded (HFMSE) 4. Six-minute walk test (6MWT) 5. Bayley Scales of Infant and Toddler Development (BSID) 6. Motor Function Measurement score (MFM32) 7. Revised Upper Limb Module (RULM) test **AND** D. The patient does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence [defined as invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in absence of an acute reversible illness, excluding perioperative ventilation]) **AND** E. The patient does NOT have any serious concomitant illness (e.g., severe liver or kidney disease, symptomatic cardiomyopathy, acute viral infection) **AND** F. The patient will NOT be using the requested agent in combination with nusinersen (Spinraza) or onasemnogene abeparvovec (Zolgensma) **AND** G. If the patient has been previously treated with nusinersen (Spinraza), use of nusinersen (Sprinraza) will be discontinued 4 months before treatment with risdiplam (Evrysdi) is started **AND**

Module	Clinical Criteria for Approval
	H. If the patient has been previously treated with onasmnogene abeparvovec (Zolgensma), the patient has NOT achieved the expected benefit from gene therapy, as demonstrated by the inability to achieve and sustain a CHOP INTEND score of more than 40 points within 3 months of gene therapy **AND** I. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** J. 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 **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 BOTH 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. ALL of the following: 1. The patient has had improvements or stabilization from baseline (prior to starting therapy with the requested agent) with the requested agent as indicated by one of the following functional assessments based on patient age and motor ability: A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) B. Hammersmith Infant Neurological Examination (HINE-2) C. Hammersmith Functional Motor Scale-Expanded (HFMSE) D. Six-minute walk test (6MWT) E. Bayley Scales of Infant and Toddler Development (BSID) F. Motor Function Measurement score (MFM32) G. Revised Upper Limb Module (RULM) test **AND** 2. The patient does not have advanced SMA (e.g. complete paralysis of limbs, permanent ventilator dependence [defined as invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in absence of an acute reversible illness, excluding perioperative ventilation]) **AND** 3. The patient does NOT have any serious concomitant illness (e.g., severe liver or kidney disease, symptomatic cardiomyopathy, acute viral infection) **AND** 4. The patient will NOT be using the requested agent in combination with nusinersen (Spinraza) or onasemnogene abeparvovec (Zolgensma) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, geneticist) 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 **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 **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: Xolair (omalizumab)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	4460306000D5	Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. 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** No 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 persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND**

Module	Clinical Criteria for Approval
	2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 3. 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 **AND** 4. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** C. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND** 2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following: A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR** B. The prescriber has provided information indicating that a reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has had an inadequate response to the FDA maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) **AND** 1. ONE of the following: A. The patient has tried and had an inadequate response to a dose above the FDA labeled maximum dose (e.g., up to 4 times the FDA labeled maximum dose) of a second-generation H-1 antihistamine **OR** B. The prescriber has provided information indicating the patient cannot be treated with a dose above the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over second-generation H-1 antihistamine therapy **OR** C. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** D. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **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 second-generation H-1 antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability

Module	Clinical Criteria for Approval
	of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **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. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** E. The patient has another FDA approved indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **OR** F. The patient has another indication that is supported in compendia for the requested agent AND the requested dose is supported in compendia for the requested indication **AND** 2. If the patient has a diagnosis of moderate to severe persistent 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. Long-acting muscarinic antagonist (LAMA) **OR** C. A Leukotriene receptor antagonist (LTRA) **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) **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**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) 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** 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 a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** 3. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **AND** B. BOTH of the following: 1. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) 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., allergist, immunologist, otolaryngologist, 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): 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 for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications **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 persistent asthma AND ALL of the following:

Module	Clinical Criteria for Approval
	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. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **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 **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** D. The patient has another FDA approved indication for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 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) 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)

Contraindicated as Concomitant Therapy
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)