MEDICAID SERVICES MANUAL TRANSMITTAL LETTER

July 26, 2022

TO:CUSTODIANS OF MEDICAID SERVICES MANUALFROM:CASEY ANGRES
MANAGER OF DIVISION COMPLIANCESUBJECT:MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs, to reflect recommendations approved at the April 28, 2022, Drug Utilization Review Board Meeting. The proposed revisions include a title change to the Monoclonal Antibody Agents section to read as Respirator and Allergy Biologics Agents; the addition of new clinical criteria to Xolair® (omalizumab) for the indication of Nasal Polyps; the addition of new clinical criteria to Hetlioz® (Tasimelteon) for indication of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS); the creation of a new section titled Movement Disorder Agents which combines the existing Austedo® (Deutetrabenazine) and Ingrezza® (Valbenazine) clinical criteria to one section, as well as the addition of new clinical criteria to Ingrezza® for the indication of Tardive Dyskenesia; and lastly, the addition of new prior authorization criteria for Vuity® (pilocarpine) 1.25% Ophthalmic Solution.

Throughout the chapter, grammar, punctuation and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These changes are effective July 27, 2022.

MATERIAL TRANSMITTED MTL N/A MSM 1200 - Prescribed Drugs

MATERIAL SUPERSEDED

MTL N/A MSM 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A	Respirator and	Updated last review date. A title change to the
Section P	Allergy Biologics	Monoclonal Antibody and the addition of new
		clinical criteria to Xolair® (omalizumab) for the
		indication of Nasal Polyps.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section III	Hetlioz® (tasimelteon)	Updated last review date. Added new clinical criteria to Hetlioz® (Tasimelteon) for indication of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).
Appendix A Section OOO	Movement Disorder Agents	Updated last review date. The creation of a new section titled Movement Disorder Agents which combines the existing Austedo® (Deutetrabenazine) and Ingrezza® (Valbenazine) clinical criteria to one section, as well as the addition of new clinical criteria to Ingrezza® for the indication of Tardive Dyskenesia.
Appendix A Section QQQ	Vuity ® (pilocarpine) 1.25% Ophthalmic Solution	Updated last review date. Added new prior authorization criteria for Vuity® (pilocarpine) 1.25% Ophthalmic Solution.

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P. Respirator and Allergy BiologicsMonoclonal Antibody Agents

Therapeutic Class: Respirator and Allergy BiologicsRespiratory Monoclonal Antibody Agents Last Reviewed by the DUR Board: April 28, 2022January 27, 2022

Respirator and Allergy Biologics Monoclonal Antibody Agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

- 1. Coverage and Limitations
 - a. Xolair® (Omalizumab)
 - 1. Approval will be given if all the following criteria are met and documented:
 - a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies;; and
 - b. All the following criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:
 - 1. The recipient must be six years of age or older; and
 - 2. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and
 - 3. The prescriber must be either a pulmonologist or allergist/ immunologist; and
 - 4. The recipient must have had an inadequate response, adverse reaction, or contraindication to inhaled, oral corticosteroids; and
 - 5. The recipient must have had an inadequate response, adverse reaction, or contraindication to a leukotriene receptor antagonist; and
 - 6. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and
 - 7. The recipient's current weight must be recorded; and
 - 8. The requested dose is appropriate for the recipient's pretreatment serum IgE and body weight (see Table 1).

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- 2. All the following criteria must be met and documented for diagnosis of chronic idiopathic urticaria (CIU):
 - a. The recipient is 12 years of age or older; and
 - b. The recipient must have had an inadequate response, adverse reaction, or contraindication to two different oral second-generation antihistamines; and
 - c. The recipient must have had an inadequate response, adverse reaction, or contraindication to an oral second-generation antihistamine in combination with a leukotriene receptor antagonist; and
 - d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist or a rheumatologist regarding the diagnosis and treatment recommendations; and
 - e. One of the following: The requested dose is:
 - 1. The request is for initiation of therapy and the dose will be 150 mg every four weeks; or
 - 2. The request is for initiation of therapy and the dose will be 300 mg every four weeks, and clinical rationale for starting therapy at 300 mg every four weeks has been provided (pharmacy review required); or
 - 3. The request is for continuation of therapy and the dose will be 150mg or 300mg every four weeks
 - 1. Initial therapy: 150 mg every four weeks or 300 mg every four weeks and clinical rationale for starting therapy at 300 mg every four weeks has been provided.
 - 2. Continuation of therapy: 150 mg or 300 mg every four weeks.

All the following criteria must be met for diagnosis of Nasal Polys (NP) and all the following:

- a. The recipient is 18 years of age or older; and
- b. The prescriber must be one of the following, or there is documentation in the recipient's medical record that a consultation regarding diagnosis and treatment recommendations was done by one of the following:

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- 1. Allergist/Immunologist; or
- 2. Dermatologist; or
- 3. Rheumatologist; and
- c. The recipient must have had an inadequate response, adverse reaction, or contraindication to at least 2 months of therapy with an intranasal corticosteroid and had inadequate response; and
- d. One of the following;
 - 1. The recipient will continue intranasal corticosteroid treatment along with omalizumab therapy; or
 - 2. The prescriber has provided valid medical rationale for not continuing intranasal corticosteroid treatment along with omalizumab therapy; or
 - 3. The request is for continuation of therapy and there is documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]
- **3.**4. Prior Authorization Guidelines:
 - a. Prior authorization approval will be for 12 months.
 - b. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>

Table 1: Dosing for Xolair® (omalizumab)*

Pre-treatment		Body Weight (kg)		
Serum IgE	30-60	>60-70	>70-90	>90-150
(IU/mL)				
≥30-100	150 mg	150 mg	150 mg	300 mg
>100-200	300 mg	300 mg	300 mg	225 mg
>200-300	300 mg	225 mg	225 mg	300 mg
>300-400	225 mg	225 mg	300 mg	
>400-500	300 mg	300 mg	375 mg	
>500-600	300 mg	375 mg		
>600-700	375 mg		DO NOT DOS	E
Every 2 Weeks D	osing			
Every 4 Weeks D	osing			
-				

- b. Nucala® (mepolizumab), Cinqair® (reslizumab)
 - 1. All the following criteria must be met and documented:

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APPENDIX A – Coverage and Limitations

DIVISION OF HEALTH CARE FINANCING AND POLICY

a.	The recip	ient	t will not use	the re	quested	antiasthmatic	monoclonal
	antibody	in	combination	with	other	antiasthmatic	monoclonal
	antibodies	s; ai	nd				

- b. The recipient must have a diagnosis of severe eosinophilicphenotype asthma; and
- c. The recipient must be of FDA indicated appropriate age:
 - 1. Mepolizumab: six years of age or older
 - 2. Reslizumab: 18 years of age or older
- d. And, the prescriber must be either a pulmonologist or allergist/ immunologist; and
- e. The recipient must be uncontrolled on current therapy including high dose corticosteroid and/or on a secondary asthma inhaler; and
- f. There is documentation of the recipient's vaccination status; and
- g. The requested dose is appropriate:
 - 1. Mepolizumab: 100 mg subcutaneously every four weeks.
 - 2. Reslizumab: 3 mg/kg via intravenous infusion of 20 to 50 minutes every four weeks.
- 2. Prior Authorization Guidelines:
 - a. Prior authorization approval will be for 12 months.
 - b. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>
- c. Nucala® (mepolizumab) for the treatment of severe asthma
 - 1. Approval will be given if all the following criteria are met and documented:
 - a. The recipient must have a diagnosis of severe asthma; and
 - b. The asthma is an eosinophilic phenotype as defined by one of the following:
 - 1. Baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter; or
 - 2. Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months; and
 - c. One of the following:

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- 1. The recipient has had at least one or more asthma exacerbations requiring systemic corticosteroid within the past 12 months; or
- 2. The recipient has had prior intubation for an asthma exacerbation; or
- 3. The recipient has had prior asthma-related hospitalization within the past 12-months; and
- d. The recipient is currently being treated with one of the following (unless there is a contraindication or intolerance to these medications)
 - 1. Both the following:
 - a. High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day); and
 - b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, long acting beta-2 agonist [LABA], theophylline); or
 - 2. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); and
- e. The recipient age is greater than or equal to six years; and
- f. The medication must be prescribed by or in consultation with one of the following:
 - 1. Pulmonologist; or
 - 2. Allergist/Immunologist
- Recertification request (the recipient must meet all the criteria)
 - a. Documentation of positive clinical response to therapy (e.g. reduction in exacerbations, improvement in forced expiratory volume in one second [FEV1], decreased use of rescue medications); and
 - b. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

- 1. Both the following:
 - a. ICS; and
 - b. Additional asthma controller medication (e.g., leukotriene receptor antagonist, long acting beta-2 agonist [LABA], theophylline); or
- 2. A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); and
- c. The medication must be prescribed by or in consultation with one of the following:
 - 1. Pulmonologist; or
 - 2. Allergist/Immunologist
- 3. Prior Authorization Guidelines:
 - a. Initial authorization will be approved for six months.
 - b. Recertification will be approved for 12 months.
 - c. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>
- d. Nucala® (mepolizumab) for the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA)
 - 1. Approval will be given if all the following criteria are met and documented:
 - a. The recipient must have a diagnosis of EGPA; and
 - b. The recipient's disease has relapsed or is refractory to standard of care therapy (i.e. corticosteroid treatment with or without immunosuppressive therapy); and
 - c. The recipient is currently receiving corticosteroid therapy; and
 - d. The medication must be prescribed or in consultation with one of the following:
 - 1. Pulmonologist; or
 - 2. Rheumatologist; or
 - 3. Allergist/Immunologist.
 - 2. Recertification Requests (the recipient must meet the following criteria)

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- a. Documentation of positive clinical response to therapy (e.g. increase in remission time).
- 3. Prior Authorization Guidelines:
 - a. Initial authorization will be approved for 12 months.
 - b. Recertification request will be approved 12 months.
 - c. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>.
- e. Fasenra® (benralizumab)
 - 1. All the following criteria must be met and documented:
 - a. The recipient must be 12 years of age or older; and
 - b. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthamtic monoclonal antibodies; and
 - c. The recipient must have a diagnosis of severe eosinophilic phenotype asthma; and
 - d. One of the following:
 - 1. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months; or
 - 2. Any prior intubation for an asthma exacerbation; or
 - 3. Prior asthma-related hospitalization within the past 12 months.
 - e. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
 - 1. Both a high-dose ICS (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or
 - 2. One maximally dosed combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/ formoterol)).
 - f. Prescribed by or in consultation with one of the following:

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- 1. Pulmonologist; or
- 2. Allergy/Immunology specialist.
- 2. Recertification Request: Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:
 - a. There is documentation of a positive clinical response (e.g., reduction in exacerbation).
 - b. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
 - 1. Both an ICS (5,E) and an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or
 - 2. A combination ICS/LABA product (e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)).
 - c. Prescribed by or in consultation with one of the following:
 - 1. Pulmonologist; or
 - 2. Allergy/Immunology specialist.
- 3. Prior Authorization Guidelines:
 - a. Initial prior authorization will be for 12 months.
 - b. Recertification request will be for 12 months.
 - c. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>
- d. Dupixent® (dupilumab)
 - 1. Approval will be given if the following criteria are met and documented:
 - a. The recipient has a diagnosis moderate of severe atopic dermatitis and all of the following:
 - 1. The medication is prescribed by or in consultation with a dermatologist or allergist/immunologist or an otolaryngologist; and
 - 2. One of the following:

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- a. Trial and failure contraindication or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, triamcinolonetramcinolone); or
- b. Trial and failure or intolerance to one of the following, unless the recipient is not a candidate for therapy (e.g. immunocompromised):
 - 1. Elidel[®] (pimecromulus) topical cream; or
 - 2. Tacrolimus topical ointment; or
- b. Diagnosis of moderate to severe asthma and all of the following:
 - 1. Recipient is six years of age or older; and
 - 2. One of the following:
 - a. The recipient is currently dependent on oral corticosteroids for the treatment of asthma:
 - 1. One or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.
 - 2. Any prior intubation authorization for an asthma exacerbation.
 - 3. Prior asthma-related hospitalization within the past 12 months; or
 - All of the following:
 - 1. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter; and
 - 2. The recipient has one of the following:
 - a. One or more asthma exacerbations requiring systematic corticosteroid within the past 12 months.
 - b. Any prior intubation for an asthma exacerbation.

b.

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- c. Prior asthma-related hospitalization within the past 12 months; and
- 3. Recipient is currently being treated with one of the following (or there is a contraindication or intolerance to all of these medications):
 - a. Both a high-dose inhaled corticosteroid (ICS) (e.g., greater than greaterthan 500 mcg fluticasone propionate equivalent/day) and an additional anadditional asthma medication controller (e.g., leukotriene receptor antagonist, longacting beta-2 agonist (LABA), theophylline); or
 - b. One maximally dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); and
- 4. Prescribed by or in consultationconsulation with a Pulmonologist or allergy/immunology specialist; or

Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) and all of the following:

1. Unless contraindicated, the recipient has had an inadequate response to two months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [Document drugs(s), dose, duration, and date of trial]; and

2. The medication will not be used in combination with another agent for CRSwNP; and

3. Prescribed by or in consultation with an allergist/immunologist

c.

- 2. Recertification Request: Authorization for continued use shall be reviewed every 12 months when the following criteria are met:
 - a. Diagnosis of moderate to severe atopic dermatitis and all the following:
 - 1. a. There is dDocumentation of positive clinical response to Dupixent therapy
 - 2. b. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
 - a. Both an ICS and additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline); or
 - b. One maximally dosed combination ICS/LABA productA combination ICS/LABA product (e.g., Advair (fluticasone Propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol))
 - Prescribed by or in consultation with a pulmonologist or Allergy/immunology specialist.
- 3. Prior Authorization Guidelines:
 - a. Initial prior authorization will be for 12 months.
 - b. Recertification request will be for 12 months.
 - c. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>

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III. Hetlioz® (tasimelteon)

Therapeutic Class: Sedative Hypnotic Last Reviewed by the DUR Board: April 28, 2022January 28, 2016

Hetlioz® (tasimelteon) is subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

2.

- a. For treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).
 - 1. Approval will be given if all following criteria are met and documented:
 - a. The recipient has a diagnosis of Non-24 disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral <u>syndrome</u>)non-24-hour sleep-wake disorder; and
 - b. The recipient is totally blind (has no light perception); and
 - c. The medication is being prescribed by or in consultation with a sleep specialist; and
 - d. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least four weeks of therapy) to a therapeutic dose of melatonin.
 - Recertification Request:
 - a. Documentation of positive clinical response to therapy.
 - 2. Prior Authorization Guidelines:
 - a. Initial prior authorization will be approved for six months.
 - b. Recertification will be approved for 12 months.
 - e.c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx
- b. For the treatment for nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).
 - 1. Approval will be given if all criteria are met and documented:
 - a. The recipient has a diagnosis of SMS; and

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- b. The recipient is at least 16 years of age and older (3 through 15 years of age for LQ suspension); and
- c. The recipient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking); and
- d. Prescribed by a neurologist or a specialist in sleep disorder; and
- e. The recipient had an adverse reaction, contraindication, or an inadequate response (after at least four weeks of therapy) to a therapeutic dose of melatonin.
- 2. Recertification Request:
 - a. Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality).
- 3. Prior Authorization Guidelines:
 - a. Initial Prior Authorization will be approved after six months.
 - b. Recertification will be approved after 12 months.
 - c. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.</u>

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OOO. Movement Disorder AgentsAustedo® (deutetrabenazine)

2.

Therapeutic Class: Movement Disorder AgentsAustedo® (deutetrabenazine) Last Reviewed by the DUR Board: January 25, 2018April 28, 2022

Movement Disorder Agents Austedo® (deutetrabenazine) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits. Austedo® is indicated for the diagnosis of chorea associated with Huntington's disease or Tardive Dyskinesia.

- 1. Austedo® (deutetrabenazine)Coverage and Limitations for Diagnosis of Chorea Associated with Huntington's Disease
 - a. For treatment of Chorea Associated with Huntington's Disease. Approval will be given if all the following criteria are met and documented:
 - 1. Initial request: Approval will be given if all the following criteria are met and documented:
 - a. The recipient must have a diagnosis of chorea associated with Huntington's disease; and
 - b. The recipient must be 18 years of age or older; and
 - c. The medication is prescribed by or in consultation with a neurologist; and
 - d. Prior authorization will not be approved for recipients who are suicidal or have untreated/inadequately treated depression, or hepatic impairment, or are currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.
 - Recertification criteria: request (the recipient must meet all of the following criteria):
 - a. Documentation of positive clinical response to therapy. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:
 - 1. Documentation of positive clinical response to Austedo® therapy.

b. Recertification will not be approved for recipients who are suicidal or have untreated/inadequately treated depression, or hepatic impairment, or are currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.

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- 3. Prior Authorization Guidelines
 - a. Initial prior authorization approval will be for 12 months.
 - b. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>
- 2.b. For the treatment of Coverage and Limitations for Diagnosis of Tardive Dyskinesia (TD).
 - 1. Approval will be given if all of the following criteria are met and documented:

3. Initial Request:

2

- a. The recipient must have a confirmed diagnosis of TD; and
- b. The recipient must be 18 years of age or older; and
- c. The medication is prescribed by or in consultation with a neurologist or psychiatrist; and
- 1. At least 60 days of stable (drug, dose) neuroleptic medication exposure (either typical or first generation antipsychotic agents, atypical or secondgeneration antipsychotic agents or certain dopamine receptor blocking drugs used in treatment of nausea and gastroparesis); and
 - Presence of involuntary athetoid or choreiform movements lasting at least 30 days; and
 - Must be prescribed by, or in consultation with, a neurologist or psychiatrist; and
 - 4.d. The recipient must have oOne of the following:
 - Persistent symptoms of TD despite a trial dose reduction, tapering or discontinuation of the offending medication; or
 - 2. The recipient is not a candidate for trial dose reduction, tapering or discontinuation of the offending medication.
- 4.2. Recertification request (the recipient must meet all the following criteria):
 - a. Documentation of positive clinical response to therapy
- 1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

. Documentation of positive clinical response to Austedo® therapy.

- **2.3**. Prior Authorization Guidelines
 - a. Initial prior authorization approval will be for three months.
 - b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx
- 2. Ingrezza® (valbenazine)
 - a. Approval will be given if the following criteria and met and documented:
 - 1. Initial request:
 - a. The recipient must have a diagnosis of severe tardive dyskinesia (TD);
 - b. The recipient must be 18 years of age or older; and
 - c. The drug must be prescribed by or in consultation with a neurologist or psychiatrist; and
 - d. One of the following:
 - 1. The recipient must have persistent symptoms of TD despite a trial of dose reduction, tapering or discontinuation of the offending medication; or
 - 2. The recipient must not be a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication.
 - b. Recertification Request:
 - 1. Documentation of positive clinical response to therapy.
 - c. Prior Authorization Guidelines:
 - 1. Initial authorization will be approved for three months.
 - 2. Recertification will be approved for 12 months.
 - 3. Prior Authorization forms are available at: <u>https://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>.

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QQQ. Ingrezza® (valbenazine) Vuity® (pilocarpine) 1.25% Ophthalmic Solution

Therapeutic Class: Ingrezza® (valbenazine)Ophthalmic Agents, Intraocular Pressure (IOP)-Modifying

Last Reviewed by the DUR Board: April 28, 2022October 19, 2017

Vuity® (pilocarpine) 1.25% Ophthalmic Solution Ingrezza® (valbenazine) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

- 1. Approval will be given if the following criteria are met and documented:
 - a. The recipient has a diagnosis of presbyopia; and
 - b. The medication prescribed by or in consultation with an ophthalmologist or optometrist; and
 - c. The recipient is unable to use corrective lenses (e.g., eyeglasses or contact lenses) confirmed by medical records (e.g., chart notes); and
 - d. Vuity will not be prescribed concurrently with any ophthalmic pilocarpine Formulations.
- 2. Recertification Request:
 - a Documentation or positive clinical response to therapy (e.g., improvement in near vision in low light conditions without loss of distance vision); and
 - b. Prescribed by or in consultation with an ophthalmologist or optometrist.
- 3. Prior Authorization Guidelines:
 - a. Initial authorization will be approved for one month.
 - b. Recertification will be approved for six months.
 - c. Prior Authorization forms are available at:
 - https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.
 - Coverage and Limitations

Approval will be given if all the following criteria are met and documented:

a. Initial request:

1. The recipient must have a diagnosis of tardive dyskinesia (TD) confirmed by the most current edition of Diagnostic and Statistical Manual of Mental Disorders (DSM), and the following:

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a. -	At least 60 days of stable (drug, dose) neuroleptic medication exposure (either typical or first generation antipsychotic agents (such as, chlorpromazine, haloperidol or fluphenazine), atypical or second-generation antipsychotic agents (such as, clozapine, risperidone, olanzapine, quetiapine or aripiprazole, or certain dopamine receptor blocking drugs used in treatment of nausea and gastroparesis (such as, prochlorperazine, promethazine or metoclopramide)); and
b.	The presence of involuntary athetoid or choreiform movements lasting at least 30 days.
1. Th	ne recipient must be 18 years of age or older; and
	e drug must be prescribed by or in consultation with a neurologist or ychiatrist; and
3. Th rec	ne recipient must have persistent symptoms of TD despite a trial of dose duction, tapering or discontinuation of the offending medication; or
	ne recipient must not be a candidate for a trial of dose reduction, tapering discontinuation of the offending medication.
b. Recertific	ation request (the recipient must meet all of the following criteria):
	athorization for continued use shall be reviewed at least every 12 months nen the following criteria are met:
2O	ocumentation of positive clinical response to Ingrezza® therapy.
c. Prior Auth	norization Guidelines
1. Ini	itial prior authorization approval will be for three months.
	ior Authorization forms are available at: ps://www.medicaid.nv.gov/providers/rx/rxforms.aspx