MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

May 31, 2022

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES, MANAGER, DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter –

The proposed changes include revisions to the existing CGRP criteria as well as updates to the Anti-Migraine Medications section to improve readability; revisions to the current prior authorization criteria for Trikafta® (elexacaftor-tezacaftor-ivacaft) within the Cystic Fibrosis Agents to conform with new FDA-approved age indication; addition of new prior authorization criteria for Opzelura® (ruxolitinib) within the Topical Immunomodulator section as well as revisions to the current prior authorization criteria for Eucrisa® (crisaborole) to conform with new FDA-approved age indication; the creation of a new Human Immunodeficiency Virus (HIV) section which includes new prior authorization criteria for Cabenuva® (cabotegravir; rilpivirine) and Vocabria® (cabotegravir); new prior authorization criteria for Zeposia® (ozanimod) for Ulcerative Colitis; revisions to the current Dupixent® (dupilumab) prior authorization criteria to conform with new FDA-approved age as well as revision to the current prior authorization criteria for Fasenra® (benralizumab) to align with the Dupixent® and Nucala® (mepolizumab) criteria; revisions to the current prior authorization for Qutenza® (capsaicin) to conform with new FDA-approved age indication of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet; addition of new prior authorization criteria for Amondys 45® (casimersen) within the Duchenne Muscular Dystrophy (DMD) agents section; and lastly revision to the Topical Androgens section to improve readability.

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 June 6, 2022.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
MTL N/A MSM 1200 - Prescribed Drugs	MTL N/A MSM 1200 - Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section L	**Immunomodulator Drugs**	Updated last review date. Added new prior authorization criteria for Zeposia® in Targeted Immunomodulator Drugs.
Appendix A Section M	**Topical Immunomodulators**	Updated last review date. New prior authorization criteria for Opzelura® and updated new indication of Eucrisa® for patients greater than or equal to three months of age for Topical Immunomodulators.
Appendix A Section P	**Monoclonal Antibody Agents**	Updated last review date. Revision of Dupixent® for new indication and update of information to make the section consistent in Respiratory Monoclonal Antibody Agents.
Appendix A Section S	**Anti-migraine Medications**	Updated last review date. Revised existing CGRP criteria. Added "(for Nurtec requests, the recipient does not have more than 18 headache days per month)." Added "the medication will not be used in combination with any other CGRP Inhibitor." Made revisions throughout the section.
Appendix A Section DD	**Topical Androgens**	Updated hierarchy and approval criteria for Xyosted® (testosterone enanthate).
Appendix A Section LL	**Cystic Fibrosis Agents**	Updated last review date. Updated prior authorization criteria for Trikafta® to conform with new FDA approved age indication for Cystic Fibrosis Agents. Added age requirements to Trikafta® (elaxacaftor/tezacaftor/ivacaftor) to match FDA-approved label.
Appendix A Section ZZ	**Human Immunodeficiency Virus (HIV) Agents**	Added new approval criteria for Cabenuva® (cabotegravir, rilpivirine) and Vocabria® (cabotegravir).
Appendix A Section MMM	**Duchenne Muscular Dystrophy (DMD) Agents**	Updated last review date. Updated due to new indication for DPN on the feet and the new addition of Amondys 45® in DMD.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section NNN	**Qutenza ® (capsaicin)**	Updated last review date. Added "The recipient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet;" to existing general criteria for Qutenza ®

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: January 27, 2022~~October 26, 2021~~

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Remicade® (infliximab)
Amevive® (alefacept)	Ilumya® (tildrakizumab)	Renflexis® (infliximab)
Arcalyst® (rilonacept)	Infle ctra® (infliximab)	Siliq® (brodalumab)
Cimzia® (certolizumab pegol)	Kevzara® (sarilumab)	Simponi® (golimumab)
Consentyx® (secukinumab)	Kineret® (ankinra)	Simponi® ARIA™ (golimumab)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Skyrizi® (risankizumab-rzaa)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Stelara® (ustekinumab)
Humira® (adalimumab)	Otezla® (apremilast)	Taltz® (ixekizumab)
Xeljanz® (tofacitinib)		

Immunomodulator Drugs 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. Approval will be given if the following criteria are met and documented:
~~1. Coverage and Limitations~~

~~2. Approval will be given if the following criteria are met and documented:~~

~~a.~~ a. For all recipients:

1. The recipient has had a negative tuberculin test; and

~~3.~~2. The recipient does not have an active infection or a history of recurring infections; and

~~4.~~3. The approval will not be given for the use of more than one biologic at a time (combination therapy); and

~~5.~~4. Each request meets the appropriate diagnosis-specific criteria (b-j).

b. Rheumatoid Arthritis (RA):

1. The recipient has a diagnosis of moderately to severely active RA; and

2. The recipient is 18 years of age or older; and

3. The recipient has had a rheumatology consultation, including the date of the visit; and one of the following:

a. The recipient has had RA for less than six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

hydroxychloroquine, leflunomide, minocycline and sulfasalazine); or

~~a.~~ b. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has moderate disease activity and has an inadequate response to a DMARD (methotrexate, hydroxychloroquine, leflunomide, minocycline or sulfasalazine); or

~~b.~~c. The recipient has had RA for greater than or equal to six months (intermediate or long-term disease duration) and has high disease activity.

~~3.~~ c. Psoriatic Arthritis:

1. The recipient has a diagnosis of moderate or severe psoriatic arthritis; and

2. The recipient is 18 years of age or older; and

~~2.~~3. The recipient has had a rheumatology consultation including the date of the visit or a dermatology consultation including the date of the visit; and

~~3.~~4. The recipient had an inadequate response or a contraindication to treatment with any one nonsteroidal anti-inflammatory (NSAID) or to any one of the following DMARDs: methotrexate, leflunomide, cyclosporine or sulfasalazine.

~~4.~~ d. Ankylosing Spondylitis:

1. The recipient has a diagnosis of ankylosing spondylitis; and

2. The recipient is 18 years or older; and

3. The recipient has had an inadequate response to NSAIDs; and

4. The recipient has had an inadequate response to any one of the DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, leflunomide, minocycline).

~~5.~~ e. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

1. The recipient has a diagnosis of moderately or severely active juvenile RA or juvenile idiopathic arthritis; and

2. The recipient is at an appropriate age, based on the requested agent, and:

a. Abatacept: Six years of age or older

b. Adalimumab, canakinumab, etanercept, tocilizumab: Two years of age or older.

~~2.~~3. And the recipient has at least five swollen joints; and

~~3.~~4. The recipient has three or more joints with limitation of motion and pain, tenderness or both; and

~~4.~~5. The recipient has had an inadequate response to one DMARD.

~~6.~~ f. Plaque Psoriasis:

1. The recipient has a diagnosis of chronic, moderate to severe plaque psoriasis; and

2. The recipient is 18 years of age of older; and

3. The agent is prescribed by a dermatologist; and

4. The recipient has failed to adequately respond to a topical agent; and

5. The recipient has failed to adequately respond to at least one oral treatment.

~~a.~~ g. Crohn's Disease:

1. The recipient has a diagnosis of moderate to severe Crohn's Disease; and

2. The recipient is at an appropriate age, based on the requested agent:

~~1.~~ a. Adalimumab, infliximab: Six years of age or older.

b. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to conventional therapy (e.g. sulfasalazine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or

4. The recipient has fistulizing Crohn's Disease.

~~b.~~h. Ulcerative Colitis (UC):

1. The recipient has a diagnosis of moderate to severe ~~ulcerative colitis~~UC; and

2. The recipient is at an appropriate age, based on the requested agent:

~~1.~~ a. Infliximab: Six years of age or older.

b. Humira: five years of age or older.

c. All others: 18 years of age or older.

3. And the recipient has failed to adequately respond to one or more of the following standard therapies:

~~1.~~ a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

4. Zeposia® (ozanimod) for diagnosis of UC

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

1. Prescribed by or in consultation with a gastroenterologist; and

2. Recipient has a diagnosis of moderately to severely active UC; and

3. Inadequate response after a 90-day trial of one of the following conventional therapies:

a. 6-mercaptopurine

b. Aminosalicylates(e.g., mesalamine, balsalazide, olsalazine)

c. Sulfasalzine

d. Azathioprine

e. Corticosteroids (e.g., budesonide, high dose steroids:

1. 40-60 mg of prednisone daily); and

4. Recipient has tried and failed two preferred immunomodulator therapies indicated for moderately to severely active UC.

~~e~~i. Cryopyrin-Associated Periodic Syndromes (CAPS): Familial Cold Autoinflammatory Syndromes (FCAS) or Muckle-Wells Syndrome (MWS):

1. The recipient has a diagnosis of FCAS or MWS; and

2. The recipient is at an appropriate age, based on the requested agent:

~~1.~~ a. Canakinumab: Four years of age or older.

b. Rilonacept: 12 years of age or older.

~~d~~j. Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID):

1. The recipient has a diagnosis of NOMID.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

M. Topical Immunomodulators

Therapeutic Class: Topical Immunomodulators
Last Reviewed by the DUR Board: January 27, 2021~~October 17, 2019~~

Topical Immunomodulators drugs are a subject to prior authorization and quantity limitations 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. Authorization will be given if the following criteria are met and documented:

~~a.~~ 1. Patient has a documented diagnosis of Atopic Dermatitis:

a. Elidel® for mild to moderate, for ages greater than or equal to~~>~~ two years.

b. Eucrisa® for mild to moderate, for ages greater than or equal to three months~~> two years~~.

c. Protopic® 0.03%; moderate to severe, for ages greater than or equal to~~>~~ two years.

~~4.~~d. Protopic® 0.1%; moderate to severe, for ages greater than or equal to~~>~~ 16 years.

~~1.~~2. The agent is ~~N~~not for chronic use.

~~2.~~3. Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.

~~2.~~4. Not recommended for use in immunocompromised patients.

~~3.~~b. Prior Authorization Guidelines:

~~2.~~1. Prior Authorization forms are available at:
https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Opzelura® (ruxolitinib)

a. Approval will be given if all the following criteria is met and documented:

1. The patient has a documented diagnosis of mild to moderate Atopic Dermatitis; and

2. Recipient is 12 years of age or older; and

3. The medication will not be used chronically; and

4. Recipient is not immunocompromised; and

5. One of the following:

   a. Disease is not adequately controlled with topical prescription therapies; or

   b. Topical prescription therapies are not advised for the patient

b. Prior Authorization Guidelines

1. Prior authorization will be approved within 12 months.

2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

P. Monoclonal Antibody Agents

Therapeutic Class: Respiratory Monoclonal Antibody Agents
Last Reviewed by the DUR Board: January 27, 2022~~January 23, 2020~~

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.

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 pre-treatment serum IgE and body weight (see Table 1).

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. The requested dose is:

      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.

3. Prior Authorization Guidelines:

   a. Prior authorization approval will be for 12 months.

   b. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

Table 1: Dosing for Xolair® (omalizumab)*

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	**>60-70**	**>70-90**	**>90-150**
≥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 DOSE**		
Every 2 Weeks Dosing				
Every 4 Weeks Dosing				

b. Nucala® (mepolizumab), Cinqair® (reslizumab)

1. All the following criteria must be met and documented:

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. The recipient must have a diagnosis of severe eosinophilic-phenotype 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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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:

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

2. 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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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)

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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

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 ~~two~~ 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:

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 ~~Patient~~ 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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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; and

2. One of the following:

a. Trial and failure contraindication or intolerance to one medium to high potency topical corticosteroid (e.g. betamethasone, tramcinolone); 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

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 month.

2. Any prior authorization for an asthma exacerbation.

3. Prior asthma-related hospitalization within the past 12 months; or

b. 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.

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., greaterthan 500 mcg fluticasone propionate equivalent/day) and anadditional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting 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 consulation with a Pulmonologist or allergy/immunology specialist; or

c. 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

2. Recertification Request: Authorization for continued use shall be reviewed every 12 months when the following criteria are met:

a. There is documentation of positive clinical response to Dupixent therapy

b. Recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medcations:

1. Both an ICS and 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))

3. 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: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~Atopic Dermatitis~~

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

~~1. The recipient must have a diagnosis of moderate to severe atopic dermatitis; and~~

~~2. One of the following:~~

~~a. Trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid(e.g. betamethasone, tramcinolone); 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® (pimecrolumus) topical cream; or~~

~~2. Tacrolimus topical ointment; and~~

~~3. The medication must be prescribed by or in consultation with one of the following:~~

~~1. Dermatologist; or~~

~~2. Allergist/Immunologist~~

~~b. Recertification request (the recipient must meet all criteria)~~

~~1. Documentation of positive clinical response to Dupixent® therapy.~~

~~c. Prior Authorization Guidelines~~

~~1. Initial authorization approval will be for 12 months.~~

~~2. Recertification approval will be for 12 months.~~

~~3. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

~~2. Eosinophilic Asthma~~

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

~~1. The recipient has a diagnosis of moderate to severe asthma; and~~

~~2. 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~~

~~3. Age is greater or equal to 12 years; and~~

~~4. One of the following:~~

~~a. The recipient has had at least one or more asthma exacerbations requiring systematic corticosteroid within the past 12 months; or~~

~~b. The recipient has had prior intubation for an asthma exacerbation; or~~

~~c. The recipient has had prior asthma-related hospitalization within the past 12 months; and~~

~~5. The recipient is currently being treated with one of the following unless there is a contraindication or ntolerance to these medications:~~

~~a. Both the following:~~

~~1. High dose ICS [e.g., greater than 500 mcg fluticasone propionate equivalent/day]; and~~

~~2. Additional asthma controller medication [e.g., leukotriene receptor antagonist, long acting 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~~

~~6. The medication must be prescribed by or in consultation with one of the following:~~

~~Pulmonologist; or~~

~~Allergist/Immunologist.~~

~~b. Recertification request (recipient must meet all the criteria):~~

~~1. Documentation of a positive clinical response to Dupixent therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications); and~~

~~2. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:~~

~~a. Both the following:~~

~~1. Inhaled corticosteroid (ICS); and~~

~~2. Additional asthma controller medication [e.g., leukotriene receptor antagonist, long acting beta-2 agonist (LABA), theophylline]; or~~

~~b. A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); and~~

~~3. The medication is prescribed by or in consultation with one of the following:~~

~~a. Pulmonologist; or~~

~~b. Allergist/Immunologist~~

~~c. Prior Authorization Guidelines~~

~~1. Initial prior authorization will be for six months.~~

~~2. Recertification approval will be for 12 months.~~

~~3. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

~~3. Oral Corticosteroid Dependent Asthma~~

~~a. Approval will be given if all the following criteria are met and documented~~

~~1. The recipient must have a diagnosis of moderate to severe asthma; and~~

~~2. The recipient is greater or equal to 12 years of age; and~~

~~3. The recipient is currently dependent on oral corticosteroids for the treatment of asthma; and~~

~~4. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:~~
~~a. Both the following:~~

~~1. High dose ICS [e.g., greater than 500 mcg fluticasone propionate equivalent/day]; and~~

~~2. Additional asthma controller medication [e.g., leukotriene receptor antagonist, long acting 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~~

~~5. The medication must be prescribed by or in consultation with one of the following:~~

~~a. Pulmonologist; or~~

~~b. Allergist/Immunologist.~~

~~b. Recertification Request (the recipient must meet all criteria)~~

~~1. Documentation of a positive clinical response to Dupixent® therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose); and~~

~~2. The recipient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:~~

~~a. Both the following:~~

~~1. ICS; and~~

~~2. Additional asthma controller medication [e.g., leukotriene receptor antagonist, long acting beta-2 agonist (LABA), theophylline]; or~~

b. A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); and

3. The medication must be prescribed by or in consultation with one of the following:

a. Pulmonologist; or

b. Allergist/Immunologist.

c. Prior Authorization Guidelines

1. Initial prior authorization approval will be for six months.

2. Recertification approval will be 12 months.

3. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

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

1. The recipient must have a diagnosis of CRSwNP; and

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

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

4. The medication must be prescribed by or in consultation with an Allergist/Immunologist

b. Recertification request (the recipient must meet all criteria)

1. Documentation of a positive clinical response to therapy; and

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

3. The medication is prescribed by or in consultation with an allergist/Immunologist.

c. Prior Authorization Guidelines

1. Initial prior authorization approval will be for 12 months.

2. Recertification approval will be for 12 months.

~~3. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

S. Anti-Migraine Medications

Therapeutic Class: Serotonin 5-HT1 receptor agonists (triptans)
Last Reviewed by the DUR Board: July 25, 2019

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: January 27, 2021~~October 26, 2021~~

Therapeutic Class: Ergot Derivitives
Last Reviewed by the DUR Board: July 22, 2021

Serotonin 5-HT1 receptor agonists commonly referred to as "triptans", CGRP Receptor Inhibitor medications and Ergot Derivitives or anti-migraine medications 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. Serotonin 5-HT1 Receptor Agonists (triptans)

a. An approved prior authorization is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

1. The recipient's current medication history documents the use of prophylactic medications for migraine headache, or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or

2. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.

a. Recipient's current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumatriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).

b. Recipients whose current medication history indicates the use of propranolol will NOT be granted prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.

c. Prior authorization will NOT be given to patients with ischemic heart disease.

b. Prior Authorization Guidelines:

1. Approval for exceeding the quantity limits on triptans will be provided for a two-month period.

2. The prior authorization must be initiated by the prescriber. The approved prior authorization must be available if requested.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications

a. CGRP General Criteria

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

a. The recipient must have one of the following:

1. Both the following:

a. The recipient has a diagnosis of episodic migraines; and

b. The recipient has four to 14 migraine days per month, but not more than 14 headache days per month: or (for Nurtec requests, the recipient does not have more than 18 headache days per month); or

2. All the following:

a. The recipient has a diagnosis of chronic migraines; and

b. The recipient has greater than or equal to 15 headache days per month, of which at least eight must be migraine days for at least three months; and

c. The recipient has been considered for medication overuse headache (MOH) and potentially offending medication(s) have been discontinued; and

b. The recipient is 18 years of age or older; and

c. The recipient has a documented history of failure (after at least a two-month trial) or an intolerance/contraindication to at least one medication from two of the following categories:

1. Evail (amitriptyline) or Effexor (venlafaxine)

2. Depakote/Depakote ER (divalproex) or Topamax (topiramate)

3. One of the following beta blockers: atenolol, propranolol, Nadolol, timolol, or metroprolol; and

d. The medication will not be used in combination with any other CGRP Inhibitor.

~~c. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist; and~~

~~d. The recipient must meet two of the following:~~

~~1. One of the following:~~

~~a. The recipient has documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or~~

~~b. The recipient has a contraindication to Elavil® (amitriptyline) and Effexor® (venlafaxine); or~~

~~2. One of the following:~~

~~a. The recipient has documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote® ER (divalproex sodium) or Topamax® (topiramate); or~~

~~b. The recipient has a contraindication to both Depakote®/Depakote® ER (divalproex sodium) and Topamax® (topiramate); or~~

~~3. One of the following:~~

~~a. The recipient has documented history of failure (after at least a two-month trial) or intolerance to one of the following beta blockers:~~

~~1. Atenolol; or~~

~~2. Propranolol; or~~

~~3. Nadolol; or~~

~~4. Timolol; or~~

~~5. Metoprolol; or~~

~~b. The recipient has a contraindication to all the following beta blockers:~~

~~1. Atenolol; or~~

~~2. Propranolol; or~~

~~3. Nadolol; or~~

~~4. Timolol; or~~

~~5.~~1. ~~Metoprolol.~~

2. Recertification Request:

a. The recipient must have a documented positive response to CGRP~~Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm) or Emgality® (galcanezumab-gnlm)~~ therapy, demonstrated by a reduction in headache frequency and/or intensity; and

b. The recipient has had a decrease in use of acute migraine medications (e.g., NSAIDs, triptans) since the start of CGRP therapy; and

~~c. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist; and~~

~~d.~~c. For chronic migraine only: The recipient continues to be monitored for MOH.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

b. CGRPs for Acute Migraines:

1. Ubrelvy® (ubrogepant), Nurtec® ODT (rimegepant).

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

1. Recipient must have a diagnosis of acute migraine with or without aura; and

2. Recipient is 18 years of age or older; and

3. The prescribed dose will not exceed two doses per migraine and treating no more than eight migraine episodes per 30 days; and

4. The recipient has had at least one trial and failure of a triptan agent; and

5. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

b. Recertification Request:

1. The recipient must have a documented positive response to the CGRP therapy; and

2. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. CGRPs for Episodic Cluster Headache

a. Emgality® (galcanezumab-gnlm)

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

a. The recipient has a diagnosis of episodic cluster headache; and

b. The recipient has experienced at least two cluster periods lasting from seven days to 365 days, separated by pain-free periods lasting at least three months.

c. The recipient is 18 years of age or older.

d. The medication must be prescribed by or in consultation with either a Neurologist or a Pain Specialist.

e. The medication will not be used in combination with any other CGRP inhibitor.

2. Recertification Request:

DD. Hormones and Hormone Modifiers

Therapeutic Class: Androgenic Agents
Last Reviewed by the DUR Board: April 25, 2019

1. Topical Androgens

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

1. Recipient is male; and

2. The medication is used for FDA-approved indication:

a. Primary (congenital or acquired); or

b. Secondary (congenital or acquired) hypogonadism; and

3. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used; and

4. Recipient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) greater than 19; and

5. Recipient does not have a hematocrit greater than 50%; and

6. Recipient does not have untreated severe obstructive sleep apnea; and

7. Recipient does not have uncontrolled or poorly controlled heart failure.

b. Prior Authorization Guidelines:

1. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

2. Xyosted™ (testosterone enanthate)

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

1. Diagnosis of Hypogonadism (e.g., testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

2. The recipient is male at birth; and

3. One of the following:

a. Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab; or both of the following:

1. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV, liver disorder, diabetes, obesity); and

2. One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (<0.17 nmol/L) or less than the reference range for the lab; or

b. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism or a genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome).

b. Diagnosis of Gender Dysphoria

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

a. Recipient is using the hormones to changes in their physical Characteristics; and

b. Recipient is a female-to-male transsexual

c. Prior Authorization Guidelines:

1. Prior authorization approval with a diagnosis of hypogonadism will be given for one year.

2. Prior authorization approval with a diagnosis of gender dysphoria will be given for six months for recipients new to testosterone therapy; or

a. Prior authorization approval will be given to recipients continuing testosterone therapy without a current authorization on file for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

~~Topical Androgens~~

~~1. Coverage and Limitations~~

~~Recipients must meet all of the criteria for coverage:~~

~~2. Criteria for approval~~

~~a. Recipient is a male;~~

b. Use is for the FDA-approved indication:

Primary (congenital or acquired) or secondary (congenital or acquired) hypogonadism with an ICD code for hypogonadism;

c. The patient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used;

d. The patient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) > 19;

e. The patient does not have a hematocrit > 50%;

f. The patient does not have untreated severe obstructive sleep apnea; and

g. The patient does not have uncontrolled or poorly controlled heart failure.

3. Prior Authorization Guidelines

a. Prior authorization approval will be for up to one year.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

Xyosted™ (testosterone enanthate)

1. Coverage and Limitations with Diagnosis of Hypogonadism

a. Diagnosis of hypogonadism (e.g. testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

b. The recipient is a male patient at birth; and

c. One of the following:

1. Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab; or both of the following:

a. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g. thyroid disorder, HIV, liver disorder, diabetes, obesity); and

b. One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab; or

2. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism or a genetic disorder known to cause hypogonadism (e.g. congenital anorchia, Klinefelter's syndrome).

2. Coverage and Limitation with Diagnosis of Gender Dysphoria

a. Diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM); and

b. The recipient is using the hormones to changes their physical characteristics; and

c. The recipient is a female-to-male transsexual.

3. Prior Authorization Guidelines

a. Length of prior authorization approval with diagnosis of hypogonadism will be for one year.

b. Length of prior authorization approval with diagnsosis of gender dysphoria will be for six months for recipients new to testosterone therapy or for 12 months for recipients continuing testosterone therapy without a current authorization on file with OptumRx.

c. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

LL. Cystic Fibrosis Agents

Therapeutic Class: Cystic Fibrosis Agents
Last Reviewed by the DUR Board: January 27, 2022~~April 30, 2020~~

Cystic Fibrosis (CF) 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. Approval will be given for a single agent concomitantly if the following criteria are met and documented:

   a. Kalydeco® (ivacaftor)

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

         a. The recipient is age appropriate according to the FDA-approved package labeling~~The recipient is six months of age or older~~; and

         b. The recipient has a diagnosis of CF; and

         c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the gene mutations listed in the FDA-approved package insert; and

         d. The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a CF care center.

      2. Recertification Request (the recipient must meet all the following criteria)

         a. Documentation of a positive clinical response to Kalydeco® therapy.

      3. Prior Authorization Guidelines:

         a. Initial request will be approved for 12 months.

         b. Recertification request will be for 12 months.

         c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

   b. Orkambi® (lumacaftor/ivacaftor)

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

         a. The recipient has a diagnosis of ~~cystic fibrosis~~CF; and

b. The recipient is age appropriate according to the FDA-approved package labeling~~The recipient is two years of age or older~~; and

c. The recipient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; and

d. The requested dose is two tablets every 12 hours; or

e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

a. Prior authorization approvals will be for one year.

b. Prior Authorizaition forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

c. Symdeko® (tezacaftor/ivacaftor)

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

a. Initial Request:

1. The recipient is age appropriate according to the FDA-approved package labeling~~The recipient is six years of age or older~~; and

2. The recipient has a documented diagnosis of CF; and

3. The medication must be prescribed by or in consultation either a Pulmonolist or a specialist associated with a CF care center.

4. One of the following:

a. The recipient is homozygous for the F508del mutation as detected by an FDA cleared CF mutation test or Clinical Laboratory Improvement Amendments (CLIA) approved facility; or

b. The recipient has one of the FDA approved package insert listed mutations on at least one allele in the (CFTR) gene as detected by FDA cleared CF mutation test or CLIA approved facility.

b. Recertification Request (the recipient must meet the following criteria):

1. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

2. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

d. Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

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

a. The recipient is age appropriate according to the FDA-approved package labeling~~12 years of age and older~~; and

b. The recipient has a documented diagnosis of CF; and

c. The recipient has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data as detected by an FDA cleared CF mutation test, or a test performed at a CLIA approved facility; and

d. The medication is prescribed by or in consultation with either a ~~Pulmanologist~~ Pulmonologist or a specialist affiliated with a CF care center.

2. Recertification Request:

a. The recipient must have documentation of a positive clinical response to Trikafta® therapy (e.g. improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations)

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

c. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

ZZ. ~~RESERVED~~Human Immunodeficiency Virus (HIV) Agents

Therapeutic Drug Class: HIV Agents
Last Reviewed by the DUR Board : January 27, 2021

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

   a. Cabenuva® (cabotegravir, rilpivirine) and Vocabria® (cabotegravir).

      1. All of the following:

         a. Diagnosis of HIV-1 infection; and

         b. Recipient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months; and

         c. Recipient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine; and

         d. Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens; and

         e. Prescribed by or in consultation with a clinician with HIV expertise; and

         f. Will not be used concurrently with other ART medications; or

      2. The agent is used for continuation of prior therapy.

   b. Prior Authorization Guidelines:

      1. Prior authorization approval will be given in 12 months.

      2. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class:Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: January 27, 2022~~July 22, 2021~~

DMD 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. Exondys 51® (eteplirsen)

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

      1. Initial request:

         a. The recipient has a diagnosis of Duchenne muscular dystrophy (DMD); and

         b. There is documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping; and

         c. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

         d. The prescribed dose does not exceed 30 milligrams per kilogram of body weight once weekly.

      2. Recertification Request (the recipient must meet all the following criteria).

         a. The recipient has been on therapy for less than 12 months; and

         b. The recipient has experienced clinically significant benefit; and

         c. The recipient is tolerating therapy; and

         d. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

         e. The medication is prescribed by or in consultation with a neurologist who has experience treating children, or all the following:

            1. The recipient has been on therapy for 12 months or more; and

            2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

            3. The recipient has experienced clinically significant benefit; and

4. The recipient is tolerating therapy; and

5. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

6. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

b. Prior Authorization Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

2. Emflaza® (deflazacort)

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

1. Initial request:

a. The recipient must have a diagnosis of (DMD); and

b. The recipient must be five years of age or older; and

c. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:

1. Documentation of a confirmed mutation of the dystrophin gene; or

2. Muscle biopsy confirming an absence of dystrophin protein; and

d. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and

e. The recipient has had at least a three-month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and

The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

b. Recertification request (the recipient must meet all the following criteria):

1. Documentation of positive clinical response to Emflaza® therapy (e.g., improvement or preservation of muscle strength); and

2. The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.

c. Prior Authorization Guidelines:

1. Initial prior authorization approval will be approved for 12 months.

2. Recertification request will be approved for 12 months.

3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. Vyondys 53® (golodirsen)

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

1. Submission of medical records (e.g. chart notes, laboratory values) documenting the following:

a. The recipient has a diagnosis of DMD; and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a neurologist who has experience treating children; and

3. The dose will not exceed 30 milligrams per kilogram of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. One of the following:

a. All the following:

1. The recipient has been on therapy for less than 12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a neurologist who has experience treating children; or

b. All the following:

1. The recipient has been on therapy for 12 months or more; and

2. Recipient experienced a benefit from therapy (e.g. disease amelioration compared to untreated patients); and

3. Recipient is tolerating therapy; and

4. Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a neurologist who has experience in treating children.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

4. Viltepso ® (viltolarsen)

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

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. The recipient has a diagnosis of DMD; and

b. The recipient has documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping; and

2. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. One of the following:

a. All of the following:

1. The recipient has been on therapy for less than 12 months; and

2. The recipient is tolerating therapy; and

3. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

4. The medication is prescribed by or in consultation with a Neurologist who has experience treating children; or

b. All of the following;

1. The recipient has been on therapy for 12 months or more; and

2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

3. The recipient is tolerating therapy; and

4. Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly; and

5. The medication is prescribed by or in consultation with a Neurologist who has experience treating children.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

5. Amondys 45® (casimersen)

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

1. Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

a. Diagnosis of Dystrophy (DMD); and

b. Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 to exon 45 skipping; and

2. Prescribed by or in consultation with a neurologist who has experience treating children; and

3. Dose will not exceed 30 milligrams per kilograms of body weight infused once weekly.

b. Recertification request (recipient must meet all criteria):

1. Recipient is tolerating therapy; and

2. Dose will not exceed 30 milligrams per kilogram of body weight infused weekly; and

3. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

3. Prior authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.

NNN. Qutenza® (capsaicin)

Therapeutic Class: Topical Neuropathic Pain Agents
Last Reviewed by the DUR Board: January 27, 2022~~January 28, 2021~~

Qutenza® (capsaicin) 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 all the following criteria is met and documented:

   a. The recipient has a diagnosis of neuropathic pain associated with postherpetic neuralgia; ~~and~~or

   b. The recipient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet; and

   ~~b~~c. The recipient has history of failure or intolerance to over-the-counter capsaicin.

2. Recertification Request (recipient must meet all criteria):

   a. At least three months have transpired since the last Qutenza® application/administration; and

   b. The recipient experienced pain relief with a prior course of therapy~~Qutenza®~~; and

   c. The recipient is experiencing a return of neuropathic pain.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification request will be approved for three months.

   c. The Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx