MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

January 31, 2023

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CASEY ANGRES
MANAGER OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on October 20, 2022, by the Drug Utilization Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria for Vivjoa® (oteseconazole) within the Anti-Fungal Agents section; addition of new prior authorization criteria for Voquenza® Dual Pak® (Vonoprazan and amoxicillin), and Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin) within the new Qualified Infection Disease Product section; addition of new prior authorization criteria for Livtencity® (maribravir) in the Antivirals section; addition of new prior authorization criteria for Cuvrior® (trientine tetrahydrochloride) within the new Copper Chelator section; addition of new prior authorization criteria for Pyrukynd® (mitapivat) within the new Pyruvate Kinase Activators section; revisions to the existing Provigil® (modafinil) and Nuvigil® (armodafinil) for the treatment of Obtructive Sleep Apnea (OSA) within the Narcolepsy Agents section; addition of new prior authorization criteria for Kynmobi® (apomorphine) in the new Anti-Parkinson's Agents section; addition of new prior authorization criteria for Amvuttra® (Vutrisiran) within the new Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B) section; revisions to the existing immunomodulator drugs criteria; revision to the existing Topical Androgens and Gender Edits, which include the addition of new prior authorization for Oral testosterone products within the Hormones and Hormones Modifiers section; addition of new prior authorization for Oxervate® (cenegermin-bkbj) within the new Ophthalmic Human Nerve Growth Factor (Q25) section.

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 February 6, 2023.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section B	**Pyruvate Kinase Activators**	Added new prior authorization criteria for Pyrukynd® (mitapivat).
Appendix A Section I	**Anti-Fungal Agents**	Added new prior authorization criteria for Vivjoa® (oteseconazole).
Appendix A Section L	**Immunomodulator Drugs**	Updated existing immunomodulator drugs clinical criteria to requiring drugs to be prescribed for an FDA-approved indication or justification for off-label use. Removed Section L(1)(d)(4).
Appendix A Section DD	**Hormones and Hormone Modifiers**	Revised existing clinical criteria for Topical Androgens to include indication for gender dysphoria. Added new clinical criteria for oral testosterone products.
Appendix A Section AAA	**Narcolepsy Agents**	Updated existing clinical criteria to include diagnosis for Obstructive Sleep Apnea (OSA).
Appendix A Section LLL	**Qualified Infection Disease Product**	Added new prior authorization criteria for Voquenza® Dual Pak® (Vonoprazan and amoxicillin) Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin).
Appendix A Section RRR	**Antivirals**	Added new prior authorization criteria for Livtencity® (maribravir).
Appendix A Section SSS	**Anti-Parkinson's Agents**	Revised the existing clinical criteria for Xadago® (safinamide). Added Kynmobi® (apomorphine). Updated section title to Anti-Parkinson's Agents.
Appendix A Section VVV	**Copper Chelator Section**	Added new prior authorization criteria for Cuvrior® (trientine tetrahydrochloride).
Appendix A Section CCCC	**Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B)**	Added new prior authorization criteria for Amvuttra® (vutrisiran).

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section DDDD	**Oxervate**	Added new clinical criteria for Oxervate® in the newly added Ophthalmic Human Nerve Growth Factor Section.
Appendix A Section 2C	**Gender Edits**	Updated existing clinical criteria for Gender Edits Section.

B. Pyrukynd® (mitapivat)~~RESERVED FOR FUTURE USE~~

Therapeutic Drug Class: Pyruvate Kinase Activators
Last Reviewed by DUR Board: October 20, 2022

Pyrukynd® (mitapivat) 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.

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

   a. Recipient is at least 18 years of age; and

   b. Recipient has a confirmed diagnosis of pyruvate kinase deficiency (PKD) as defined by the documented presence of at least two variant alleles in the PKLR gene, of which at least one was a missense variant; and

   c. Recipient is not homozygous for the c.1436G>A (p.R479H) variant; and

   d. Recipient does not have two non-missense variants (without the presence of another missense variant) in the PKLR gene; and

   e. Recipient has a baseline serum hemoglobin level less than 10g/dL or required more than six transfusions in the prior year; and

   f. Other causes of hemolytic anemia have been ruled out (e.g., immune hemolysis, other enzyme deficiencies, vitamin/mineral deficiencies); and

   g. Recipient does not have moderate or severe hepatic impairment; and

   h. Prescriber will advise patients currently on hormonal contraceptives to use an alternative non-hormonal contraceptive method or add a barrier method of contraception during treatment; and

   i. Quantity limit is 60 tablets/30 day (max dose 100mg/day).

2. Recertification Request:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient has shown a beneficial response to therapy compared to pre-treatment baseline in one or more of the following:

      1. Hemoglobin (Hb) response (defined as a greater than or equal to 1.5g/dL increase in Hb level without transfusion over a four week or longer time period; or

2. Transfusion reduction response (defined as a greater than or equal to 33% reduction in the number of red blood cell [RBC] units transfused compared to historical transfusion burden); or

3. Recipient had an increase in Hb and/or decrease in transfusion requirement, to a lesser extent than the above, and also had an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin).

c. Recertification will be approved for six months.

3. Prior authorization guidelines:

a. Prior authorization will be approved for six months.

I. Anti-Fungal Agents

Therapeutic Class: Antifungal Agents
Last Reviewed by the DUR: ~~July 28, 2022~~October 20, 2022

Anti-Fungal 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. Topical Agents (Jublia® (efinaconazole), Kerydin® (tavaborole))

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

      1. Diagnosis of onychomycosis; and

      2. At least one of the following:

         a. The recipient is experiencing pain which limits normal activity; or

         b. The recipient has diabetes; or

         c. The recipient has significant peripheral vascular compromise; or

         d. The recipient's disease associated with immunosuppression; or

         e. The recipient's disease is iatrogenically induced; and

            1. An inadequate response (to an appropriate length or therapy), and adverse reaction, a contraindication to use, or a clinical reason either oral terbinafine or itraconazole cannot be used; and

            2. The recipient must have an adverse reaction or have a contraindication to ciclopirox 8% solution.

2. Oral Agents (Sporanox®, Lamisil®)

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

      1. An adequate response (to an appropriate length of therapy), an adverse reaction, a contraindication to use, or a clinical reason either oral terbinafine or itraconazole cannot be used; and

      2. The recipient must have had an adverse reaction or have a contraindication to ciclopirox 8% solution.

   b. Prior Authorization Guidelines

      1. Prior authorization will be approved for 48 weeks.

3. Brexafemme® (ibrexafungerp)

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

1. Recipient is postmenarchal female 12 years of age or older; and

2. Diagnosis of vulvovaginal candidiasis (VVC); and

3. Females of reproductive potential must have negative pregnancy test; and

4. Recipient must have an adequate trial and failure, contraindication, resistance, or intolerance of at least single dose 150mg oral fluconazole.

5. Quantity Limit is four tablets.

b. Recertification Request:

1. Coverage is not renewable.

c. Prior Authorization Guidelines:

1. Prior Authorization will be for one day.

4. Vivjoa® (oteseconazole)

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

1. Recipient has a diagnosis of recurrent vulvoginal candidiasis with greater than or equal to three episodes of vulvovaginal candidiasis (VVC) in a 12-month period; and

2. Recipient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); and

3. Recipient must not have hypersensitivity to any component of the product; and

4. Recipient is not pregnant; and

5. Recipient is not lactating; and

6. Recipient has tried and failed or has contraindication or intolerance to maintenance antifungal therapy with oral fluconazole for six months; and

7. Quantity limit is 18 tablets per treatment course.

b. Recertification Request:

1. Coverage is not renewable.

c. Prior Authorization Guidelines:

1. Prior Authorization will be for 12 weeks.

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: October 20, 2022~~January 27, 2022~~

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Remicade® (infliximab)
Amevive® (alefacept)	Ilumya® (tildrakizumab)	Renflexis® (infliximab)
Arcalyst® (rilonacept)	Inflectra® (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:

   a. For all recipients:

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

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

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

      4. The requested medication is being prescribed for an FDA-approved indication or the prescriber has provided clinical justification for off-label usage.

      ~~4.~~5. 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

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

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.

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

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

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.

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).~~

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

DD. Hormones and Hormone Modifiers

Therapeutic Class: Androgenic Agents
Last Reviewed by the DUR Board: October 20, 2022~~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. Diagnosis of Gender Dysphoria:~~Prior Authorization Guidelines:~~

1. Approval will be given if the following criteria are met and documented:~~Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx.~~

a. Recipient is using the hormones to change their physical characteristics; and

b. Recipient is a female-to-male transsexual.

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.

3. Oral Testosterone Products

a. Hypogonadism:

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

   a. The recipient is greater than 18 years of age; and

   b. Recipient is male; and

   c. Recipient has a diagnosis of primary hypogonadism or hypogonadotropic hypogonadism (congenital or acquired); and

   d. Recipient has history of failure, contraindication, or intolerance to both testosterone cypionate and testosterone enanthate injection; and

   e. Recipient has signs/symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes); and

   f. Recipient does not have "age-related hypogonadism' or another hypogonadal condition not associated with structural or genetic etiologies; and

   g. Recipient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (initial approval only); and

   h. Recipient is only receiving one androgen or anabolic agent; and

   i. Recipient does not have current or history of breast cancer; and

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

   k. Recipient does not have uncontrolled hypertension or heart failure; and

   l. Recipient does not have uncontrolled obstructive sleep apnea; and

   m. Medication is prescribed by or in consultation with an endocrinologist or urologist.

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. Recertification Request:

1. Recipient must continue to meet above criteria; and

2. Recipient must have disease improvement and/or stabilization.

d. Prior Authorization Guidelines:

1. Prior authorization approval will be for 12 months.

AAA. Narcolepsy Agents

Therapeutic Class: Narcolepsy Agents (non-stimulants)
Last Reviewed by the DUR Board: October 20, 2022~~July 28, 2022~~

Narcolepsy Agents are subject to prior authorizations 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. Provigil® (modafinil) and Nuvigil ® (armodafinil)

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

      1. The recipient has a diagnosis of narcolepsy; or

         a. Obstructive Sleep Apnea (OSA); or

         b. Excessive sleepiness associated with shift work disorder.

   b. For treatment of OSA:

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

         a. The recipient must have a diagnosis of OSA defined by one of the following:

            1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study unless the prescriber provides justification confirming that a sleep study would not be feasible; or

            2. Both the following:

               a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

               b. One of the following signs/symptoms are present:

                  1. Daytime sleepiness; or

                  2. Nonrestorative sleep; or

                  3. Fatigue; or

                  4. Insomnia; or

~~4.~~5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

~~b~~c. Recertification Request:

1. Documentation of positive clinical response to therapy.

2. For OSA: The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP).

~~c~~d. Prior Authorization Guidelines:

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

2. Xyrem® (sodium oxybate)

a. The recipient has tried and failed on Provigil® (modafinil) or Nuvigil® (armodafinil); and/or

b. The recipient has a diagnosis of narcolepsy with cataplexy; and

c. The drug was prescribed by or in consultation with a neurologist or sleep specialist.

d. Prior Authorization Guidelines

1. Prior authorization approvals will be for 12 months.

3. Sunosi® (solriamfetol)

a. For treatment of Narcolepsy

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

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has had trial and failure, contraindication, or intolerance to both of the following:

1. modafinil; and

2. armodafinil.

2. Recertification Request:

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for 12 months.

b. Recertification request will be approved for 12 months.

b. For treatment of OSA

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

a. The recipient must have a diagnosis of OSA defined by one of the following:

1. The recipient has had 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); or

2. Both the following:

a. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. One of the following signs/symptoms are present:

1. Daytime sleepiness; or

2. Nonrestorative sleep; or

3. Fatigue; or

4. Insomnia; or

5. Waking up with breath holding, gasping, or choking; or

6. Habitual snoring noted by a bed partner or other observer; or

7. Observed apnea; and

c. Both the following:

1. The recipient has used a standard treatment(s) for the underlying obstruction for one month or longer (e.g., CPAP, BiPAP); and

2. The recipient is fully compliant with ongoing treatment(s) for the underlying airway obstruction; and

d. The recipient has had a trial and failure, contraindication, or intolerance to both of the following:

1. Modafinil; and

2. Armodafinil.

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

a. Documentation of positive clinical response to ~~Sunosi®~~ therapy; and

b. The recipient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction. (e.g., CPAP, BiPAP)

~~2.~~3. Prior Authorization Guidelines

a. Initial request will be approved for six months.

b. Recertification request will be approved for for six months.

3. Wakix® (pitolisant)

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

1. The recipient has a documented diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

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

b. Recertification Requests:

1. The recipient must have documentation of positive clinical response to Wakix® therapy.

c. Prior Authorization Guidelines:

1. Initial request will be approved for six months.

2. Recertification request will be approved for 12 months.

~~3.~~4. Xywav® (calcium, magnesium, potassium, and sodium oxybates)

a. Narcolepsy with Cataplexy (Narcolepsy Type 1).

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

a. The recipient has a diagnosis of narcolepsy confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible); and

b. The recipient has present symptoms of cataplexy; and

c. The recipient has symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep); and

d. The medication is prescribed by or in consultation with either a Neurologist, a Psychiatrist, or a Sleep Medicine Specialist.

2. Recertification Request:

a. The recipient has documentation demonstrating a reduction in the frequency of cataplexy attacks associate with therapy; or

b. The recipient has documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.

3. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification request will be approved for 12 months.

b. Narcolepsy without Cataplexy (Narcolepsy Type 2)

LLL. Voquenza® Dual Pak® (Vonoprazan and amoxicillin), Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin)~~RESERVED~~

Therapeutic Drug Class: Qualified Infection Disease Product
Last Reviewed by DUR Board: October 20, 2022

Voquenza® Dual Pak® (Vonoprazan and amoxicillin), Voquenza® Triple Pak® (Vonoprazan, amoxicillin, and clarithromycin) 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. Recipient is 18 years or age or older; and

   b. Recipient has a confirmed diagnosis of Helicobacter pylori (H. pylori) infection; and

   c. Recipient must not have hypersensitivity or cross-hypersensitivity to any component or drug class of the product (e.g., penicillins, cephalosporings, macrolides); and

   d. Treatment will not be used concurrently with rilpivrine-containing products; and

   e. For vonoprazan/amoxicillin/clarithromycin requests (Voquenza® Triple Pak®), the patient does not have a history or hepatic dysfunction or cholestatic jaundice associated with prior use of clarithromycin; and

   f. For vonoprazan/amoxicillin/clarithromycin (Voquenza® Triple Pak®), the patient does not have ventricular cardiac arrythmia, prolongation of the QT interval, or proarrhythmic condition (e.g., uncorrected hypokalemia or hypomagnesemia); and

   g. Recipient must have an adequate trial and failure of, or relevant medical reason for not using, proton pump inhibitor-based H.pylori treatment regimen; and

   h. Baseline renal and hepatic function laboratory tests have been obtained; and

   i. Quantity limit of 14-day supply.

2. Recertification Request:

   a. Coverage is not renewable.

3. Prior Authorization Guidelines:

   a. Prior Authorization will be given for 14 days.

RRR. Livtencity® (Maribravir)~~RESERVED FOR FUTURE USE~~

Therapeutic Drug Class: Antivirals
Last Reviewed by DUR Board: October 20, 2022

Livencity® (maribravir) 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. Recipient is greater than or equal to 12 years of age; and

   b. Recipient must weigh greater than 35 kilograms (kg); and

   c. Recipient of a hematopoietic stem cell or solid organ transplant; and

   d. Recipient has documented cytomegalovirus (CMV) infection in whole blood or plasma (screening value greater than or equal to 2,730 IU/mL in whole blood or greater than or equal to 910 IU/mL in plasma) in two consecutive assessments separated by greater than or equal to one day; and

   e. Recipient has current CMV infection that is refractory (documented failure to achieve greater than 1 log10 decrease in CMV deoxyribonucleic acid [DNA] level in whole blood or plasma after greater than or equal to 14 days treatment) to anti-CMV treatment agents (ganciclovir, valganciclovir, cidofovir, or foscarnet), even with documented genetic mutations associated with resistance; and

   f. Maribravir will not be coadministered with ganciclovir or valganciclovir; and

   g. Recipient will be monitored for clinically important drug interactions that could results in decreased therapeutic effect of maribravir.

2. Recertification Request:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient must have disease improvement and/or stabilization or improvement in the slope of decline (greater than 1 log10 decrease in CMV DNA level in whole blood or plasma after 14 days or longer treatment); and

   c. Recipient has not experienced any treatment-restricting adverse effects (e.g., dysgeusia, diarrhea, nausea, and recurrence of underlying disease); and

   d. Recipient is not a non-responder (resistant) to maribravir.

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

SSS. Anti-Parkinson's Agents ~~Xadago® (safinamide)~~

Therapeutic Class: Anti-Parkinson's Agents~~Xadago® (safinamide)~~
Last Reviewed by the DUR Board: October 20, 2022~~October 19, 2017~~

Anti-Parkinson's Agents ~~Xadago® (safinamide)~~ 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. Xadago ® (safinamide)~~Coverage and Limitations~~

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

      1. The recipient must have a diagnosis of Parkinson's disease: and

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

      3. Documented continued Levodopa and/or other dopaminergic treatments; and

      4. Recipient reports greater than 1.5 hours per day "off" episodes ("off" episodes refer to "end-of-dose wearing off" and unpredictable "on/off" episodes); and

      5. Recipient must not also be taking any of the following drugs: other MAOIs or other drugs that are potent inhibitors of MAOI (e.g., linezolid), opioid drugs (e.g., tramadol meperidine and related derivatives), selective norepinephrine reuptake inhibitors (SNRIs), tri- or tetra-cyclic or triazolopyridine antidepressants (TCAs), cyclobenzaprine, methylphenidate, amphetamine and their derivatives, St. John's wort or dextromethorphan; and

      6. The recipient must not have severe hepatic impairment (e.g., Child-Pugh C).

   b. Recertification Request:

      1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

         a. Documentation of positive clinical response to Xadago® therapy; and

         b. Documented continued Levodopa and/or other dopaminergic treatments.

   c. Prior Authorization Guidelines:

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

2. Kynmobi® (apomorphine)

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

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

2. Recipient has a documented diagnosis of Parkinson's disease (PD); and

3. Recipient is experiencing "off" episodes of PD at least two hours per day on average; and

4. Recipient is on a stable levodopa-based therapy; and

5. Recipients will not be on a concomitant 5HT3 antagonists (e.g., ondansetron, granisetron, dolansetron, palonosetron, alosetron); and

6. Recipient will be prescribed a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide) for initial therapy; and

7. Recipient does not have a major psychotic disorder.

b. Recertification Request:

1. Recipient must continue to meet the initial criteria above; and

2. Recipient has demonstrated a beneficial response to therapy (e.g., decrease in frequency and duration from baseline in motor fluctuations ["off episodes]); and

3. Recipient is absent of unacceptable toxicity from the drug (e.g., nausea or vomiting, oral mucosal irritation or stomatitis, decreased impulse control, syncope or hypotension, hallucinations or psychotic-like behavior, QTc prolongation, fibrotic complications, priapism, retinal atrophy or degeneration, excessive daytime sleepiness including falling asleep during activities that require active participation).

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for 12 months.

~~a. Initial request:~~

~~1. The recipient must have a diagnosis of Parkinson's disease; and~~

~~2. The recipient must be five years of age or older; and~~

3. Documented continued Levodopa and/or other dopaminergic treatments; and

4. Recipient reports greater than 1.5 hours per day of "off" episodes ("off" episodes refer to "end-of-dose wearing off" and unpredictable "on/off" episodes); and

5. Recipient must not also be taking any of the following drugs: other MAOIs, or other drugs that are potent inhibitors of MAOI (e.g., linezolid), opioid drugs (e.g., tramadol, meperidine and related derivatives), selective norepinephrine reuptake inhibitors (SNRIs), tri- or tetra-cyclic or triazolopyridine antidepressants (TCAs), cyclobenzaprine, methylphenidate, amphetamine and their derivatives, St. John's wort or dextromethorphan; and

6. The recipient must not have severe hepatic impairment (e.g., Child-Pugh C).

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

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

a. Documentation of positive clinical response to Xadago® therapy; and

b. Documented continued Levodopa and/or other dopaminergic treatments.

c. Prior Authorization Guidelines

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

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

VVV. Cuvrior® (trientine tetrahydrochloride) ~~(RESERVED FOR FUTURE USE)~~

Therapeutic Drug Class: Copper Chelator
Last Reviewed by DUR Board: October 20, 2022

Cuvrior® (trientine tetrahydrochloride) 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 once the following criteria are met and documented:

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

   b. Recipient has Wilson's disease (defined by a prior or current Leipzig score of greater than or equal to four); and

   c. Recipient is being treated with penicillamine for greater than or equal to one year at a stable dose and regimen for greater than or equal to four months, and recipient is tolerating penicillamine and adequately controlled (e.g., serum non-ceruloplasmin copper [NCC] level between greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour urinary copper excretion [UCE] of between levels greater than or equal to 100 and less than or equal to 900 mcg/24 hours); and

   d. Penicillamine will be discontinued before initiating Cuvrior; and

   e. Recipient will not concurrently use another formulation of trientine (e.g., Syprine, generics); and

   f. Prescribed by or in consultation with a hepatologist or neurologist; and

   g. Quantity limit is 300 tablets/30 days (max daily dose 3,000mg).

2. Recertification Request:

   a. Recipient must continue to meet the above criteria; and

   b. Recipient has evidence of effectiveness of therapy (e.g., as assessed by serum NCC level between greater than or equal to 25 and less than or equal to 150 mcg/L or 24-hour UCE levels greater than or equal to 100 and less than or equal to 900 mcg/24 hours); and

   c. Recipient does not exhibit clinical manifestations of advancement of Wilson's disease from baseline (e.g., jaundice, edema, ascites, esophageal varices, liver failure, central nervous system symptoms); and

   d. Recipient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity reactions, copper deficiency, iron deficiency).

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

CCCC. Amvuttra® (Vutrisiran) ~~(RESERVED FOR FUTURE USE)~~

Therapeutic Drug Class: Amyloidosis-Agents Transthyretin (TTR) Suppression (P9B)
Last Reviewed by DUR Board: October 20, 2022

Amvuttra® (Vutrisiran) 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.

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

    a. Recipient is greater than or equal to 18 years of age; and

    b. Recipient will receive supplementation with vitamin A as the recommended daily allowance during vutrisiran therapy; and

    c. Vutrisiran must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen [Tegsedi®], tafamidis [Vyndamax®, Vyndaqel®], patisiran [Onpattro®]); and

    d. Recipient has a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis/FAP (familial amyloidotic polyneuropathy) as documented by amyloid deposition on tissue biopsy and identification of a pathogenic TTR variant using molecular genetic testing; and

    e. Polyneuropathy is demonstrated by greater than or equal to two of the following criteria:

        1. Subjective patient symptoms are suggestive of neuropathy; or

        2. Abnormal nerve conduction studies are consistent with polyneuropathy; or

        3. Abnormal neurological examination is suggestive of neuropathy; and

    f. Recipient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; and

    g. Baseline strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council [MRC] muscle strength); and

    h. Recipient has not had an orthotopic liver transplant (OLT); and

    i. Quantity limit is one syringe every three months.

2. Recertification Request:

    a. Recipient continues to meet the above criteria; and

b. Recipient is absent of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ocular symptoms related to hypovitaminosis A, etc.; and

c. Recipient has experienced disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in greater than or equal to one of the following:

1. Signs and symptoms of neuropathy; or

2. MRC muscle strength.

d. Recertification will be approved for six months.

3. Prior Authorization Guidelines:

a. Prior authorization will be approved for six months.

DDDD. Oxervate® (Cenegermin-bkbj) ~~(RESERVED FOR FUTURE USE)~~

Therpeutic Drug Class: Ophthalmic Human Nerve Growth Factor (Q25)
Last Reviewed by DUR Board: October 20, 2022

Oxervate® (Cenegermin-bkbj) 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.

1. Approval will be given if the following criteria are met and documented:
    a. Recipient must be greater than or equal to two years of age; and
    b. Recipient must have a diagnosis of moderate to severe (stage two or stage three) neurotrophic keratitis (NK); and
    c. Prescribed by or in consultation with an ophthalmologist; and
    d. Prescriber attestation that patient or caregiver has been counseled on proper administration technique; and
    e. Quantity Limit of eight kits per affected eye per lifetime.
2. Renewal Criteria:
    a. Coverage not renewable.
3. Prior Authorization Guidelines:
    a. Prior authorization will be approved for eight weeks.

2. MEDICATIONS WITH GENDER/AGE EDITS

A. Prenatal Vitamins

1. Payable only for female recipients.

B. Oral/Topical Contraceptives

1. Payable only for female recipients.

C. Gender Edits

1. Hormones

a. Estrogen – payable only for female recipients.

b. Progestins – payable only for female recipients.

c. Estrogen and Androgen Combinations – payable only for female recipients.

d. Estrogen and Progestin Combinations – payable only for female recipients.

e. Contraceptive Hormones – payable only for female recipients.

f. ~~Transdermal~~ Testosterone – payable only for male recipients.

g. Androgen Hormone Inhibitor – payable only for male recipients.

2. Exception to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.