MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

October 25, 2022

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 July 28, 2022 by the Drug Utilization Review (DUR) Board. The proposed changes include the addition of new prior authorization criteria and combination for Invega Hafyera®(paliperidone palmitate) and Invega Trinza® in the Antipsychotics: Atypical Section; added new prior authorization criteria for Brexafemme® (ibrexafyngerp) in the Antifungal Antibiotics Section; adoption of new drug update for Ponvory® (ponesimod) within the Multiple Sclerosis Agents Section; new prior authorization criteria for Bylvay®(odevixibat) and Livmarli®(Maralixibat) in the new Ileal Bile Acid Transporter Inhibitor Section; updated existing criteria for Opzelura®(ruxolitinib) in the Topical Immunomodulator Section; added new prior authorization criteria for Skytrofa® (lonapegsomatropin-TCGD) in the Growth Hormone Section; updated existing criteria for Analgesics in the Immediate-Release Fentanyl Products Section; added Trudhesa® in the existing criteria for Ergot Derivatives within the Anti-Migraine Medication Section; updated existing criteria in the Anti-Fungal Onychomycosis Section; updated existing criteria for Cabenuva® within the Human Immunodeficiency Virus (HIV) Agents Section; eliminated the section for Bevyxxa® (betrixaban); updated age indication criteria for Evrysdi® within the Spinal Muscular Atrophy (SMA) Agents 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 October 31, 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MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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 B	**Bevyxxa®**	Eliminated the section for Bevyxxa® (betrixaban).
Appendix A Section D	**Growth Hormone Section**	Added new prior authorization criteria for Skytrofa® (lonapegsomatropin-tcgd). Removal of the forms link.
Appendix A Section G	**Immediate-Release Fentanyl Products**	Updated existing criteria for Analgesics. Removal of the forms link.
Appendix A Section I	**Antifungal Antibiotics**	Added new prior authorization criteria for Brexafemme® (ibrexafyngerp) and updated existing criteria in the Anti-Fungal Onychomycosis Section. Removal of the forms link.
Appendix A Section K	**Spinal Muscular Atrophy (SMA) Agents**	Updated age indication criteria for Evrysdi®. Removal of the forms link.
Appendix A Section M	**Topical Immunomodulator Section**	Updated existing criteria for Opzelura®(ruxolitinib). Removal of the forms link.
Appendix A Section S	**Anti-Migraine Medication**	Added Trudhesa® in the existing criteria for Ergot Derivatives. Removal of the forms link.
Appendix A Section CC	**Multiple Sclerosis Agents**	New prior authorization criteria for Ponvory® (ponesimod) within the Multiple Sclerosis Agents Section. Removal of the forms link.
Appendix A Section ZZ	**Human Immunodeficiency Virus**	Updated existing criteria for Cabenuva®. Removal of the forms link.
Appendix A Section FFF	**Antipsychotic Drugs: Atypical**	Renamed the section. New prior authorization criteria and combination of Invega Hafyera® (paliperidone palmitate) and Invega Trinza under the same Antipsychotic Drugs Section. Removal of the forms link.
Appendix A Section HHH	**Ileal Bile Acid Transporter Inhibitor**	New prior authorization criteria for Bylvay®(odevixibat) and Livmarli®(Maralixibat).

B. RESERVED FOR FUTURE USE ~~Bevyxxa® (betrixaban)~~

~~Therapeutic Class: Oral Anticoagulants~~
~~Last Reviewed by the DUR Board: January 25, 2018~~

~~Bevyxxa® (betrixaban) 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. Coverage and Limitations~~

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

~~a. Initial request:~~

~~1. The recipient has a diagnosis of prophylaxis of venous thromboembolism (VTE); and~~

~~2. The recipient must be 18 years of age or older; and~~

~~3. The recipient has received Bevyxxa® during hospitalization and will be continuing Bevyxxa® therapy following discharge from the hospital; and~~

~~4. The recipient is at risk for thromboembolic complications due to moderate or severe restricted mobility and has other risk factors of VTE; and~~

~~5. The recipient has not received a cumulative 42 days of Bevyxxa® therapy.~~

~~2. Prior Authorization Guidelines~~

~~a. Prior authorization approvals will be for:~~

~~1. Prior Authorization Request: Up to a total treatment duration of 42 days.~~

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

D. Growth Hormones

Therapeutic Class: Growth Hormone

Last Reviewed by the DUR Board: July 28, 2022~~July 23,2020~~

Growth Hormones are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act 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. Approval will be given if the following criteria are met and documented:

1. Children (with open epiphyses and with remaining growth potential) must meet all ~~of~~ the following:

a. The recipient has had an evaluation by a pediatric endocrinologist or pediatric nephrologist with a recommendation for growth hormone therapy; and

b. The recipient has had an evaluation ruling out all other causes for short stature; and

c. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids, or gonadotropic hormones.

The recipient must then meet one of the following:

1. The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is at least two standard deviations below the mean or below the fifth percentile for the patient's age and gender and the bone age is less than 16 years for male recipients or less than 14 years for female recipients; or

2. The recipient has a diagnosis of Prader-Willi Syndrome; or

3. The recipient has a diagnosis of Turner Syndrome, is female and has a bone age of less than 14 years; or

4. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute), and their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

5. The recipient has a diagnosis of being small for gestational age, the recipient is two years of age or older, and the height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or

6. The recipient is a newborn infant with evidence of hypoglycemia, and has low growth hormone level (<20 ng/mL), low for age insulin like growth factor (IGF)-1 or IGF binding protein (BP) 3 (no stimulation test required for infants); or

7. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender and their bone age is less than 16 years for male or less than 14 years for female.

   And recipient must meet one of the following:

   a. The recipient has failed two growth hormone stimulation tests (<10 ng/mL); or

   b. The recipient has failed one growth hormone stimulation test (<10 ng/mL) and one IGF-1 or IGFBP-3 test; or

   c. The recipient has failed one growth hormone stimulation test (<10 ng/mL) or IGF-1 or IGFBP-3 test and they have deficiencies in three or more pituitary axes (e.g., thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), adrenocorticotropic hormone (ACTH) or antidiuretic hormone (ADH)).

2. Adults (with closed epiphyses, and no remaining growth potential) must meet all ~~of~~ the following:

   a. The recipient is being evaluated by an endocrinologist; and

   b. The recipient is receiving adequate replacement therapy for any other pituitary hormone deficiencies, such as thyroid, glucocorticoids, or gonadotropic hormones; and

   c. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to

structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma, or cranial irradiation); and

The recipient must then meet one of the following:

1. The recipient has failed two growth hormone stimulation tests (<5 ng/mL); or

2. The recipient has failed one growth hormone stimulation test (<5 ng/mL) and one IGF-1 or IGFBP-3 test; or

3. The recipient has failed one growth hormone stimulation test (<5 ng/mL) or IGFBP-3 test and has deficiencies in three or more pituitary axes (i.e., TSH, LH, FSH, ACTH, ADH), and has severe clinical manifestations of growth hormone deficiency as evident by alterations in body composition (e.g., decreased lean body mass, increased body fat), cardiovascular function (e.g., reduced cardiac output, lipid abnormalities) or bone mineral density.

3. Continued authorization will be given for recipients (up to age 21, with remaining growth potential) who meet all ~~of~~ the following:

a. The recipient has a diagnosis of chronic renal insufficiency, growth hormone deficiency, hypothalamic pituitary disease, newborn infant with evidence of hypoglycemia, Noonan Syndrome, Prader-Willi Syndrome, small for gestational age or Turner Syndrome; and

b. The recipient's epiphyses are open; and

c. The recipient's growth rate on treatment is at least 2.5 cm/year; and

d. The recipient does not have evidence of an expanding lesion or tumor formation; and

e. The recipient has not undergone a renal transplant.

4. Continued authorization will be given for recipients (age 21 years and older, with closed epiphyses and no remaining growth potential) who meet all ~~of~~ the following:

a. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease; and

b. There is documentation of improvement in clinical manifestations associated with growth hormone deficiency

5. Prior Authorization Guidelines

a. Initial prior authorization will be for six months.

b. Recertification approval will be for 12 months.

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

b. Serostim® (somatropin)

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

a. The recipient has a diagnosis of Human Immune Deficiency Virus (HIV) with wasting or cachexia; and

b. The medication is indicated to increase lean body mass, body weight and physical endurance; and

c. The recipient is receiving and is compliant with antiretroviral therapy; and

d. The recipient has experienced an involuntary weight loss of >10% pre-illness baseline or they have a body mass index of <20 kg/m^2; and

e. The recipient has experienced an adverse event, allergy, or inadequate response to megestrol acetate, or the recipient has a contraindication to treatment with this agent; and

f. The recipient has experienced an adverse event, allergy, or inadequate response to an anabolic steroid (e.g., testosterone, oxandrolone, nandrolone) or the recipient has a contraindication to treatment with these agents.

2. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 weeks.

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

c. Zorbtive® (somatropin)

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

a. The recipient has a diagnosis of short bowel syndrome; and

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

c. The medication is being prescribed by or following a consultation with a gastroenterologist; and

d. The recipient is receiving specialized nutritional support (e.g., high carbohydrate, low-fat diets via enteral or parenteral nutrition).

2. Prior Authorization Guidelines

a. Initial authorization will be approved for six months.

b. Recertification request will be approved for 12 months.

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

d. Somavert® (pegvisomant)

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

a. The recipient has a diagnosis of acromegaly; and

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

c. One of the following:

1. The recipient has an inadequate response to one of the following:

a. Surgery; or

b. Radiation Therapy; or

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; or

2. The recipient is not a candidate for all the following:

a. Surgery; and

b. Radiation Therapy; and

c. Dopamine agonist (e.g. bromocriptine, cabergoline) therapy; and

d. The recipient has tried and failed, a contraindication, or intolerance to generic octreotide (a somatostatin analogue); and

e. The medication is prescribed by or in consultation with an endocrinologist.

2. Recertification Criteria:

a. The recipient must meet the following:

1. The recipient must have a documented positive clinical response to Somavert® therapy (e.g. biochemical control; decrease or normalization of IGF-1 levels).

3. Prior Authorization Guidelines:

a. Initial authorization will be approved for 12 weeks.

b. Recertification approval will be approved for 12 months.

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

e. Skytrofa® (Lonapegsomatropin-tcgd)

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

a. Recipient is one year or age or older; and

b. Recipient's weight is greater than 11.5kg; and

c. Recipient has growth failure secondary to growth hormone deficiency (GHD); and

d. Recipient has short stature as defined by height that is greater than or equal to two standard deviations below the mean for chronological age; and

1. Recipient has hypothalamic-pituitary defects (e.g., major congenital malformation, tumor, or irradiation) and a deficiency of greater than or equal to one additional pituitary hormone; or

2. Recipient had an inadequate response to growth hormone (GH) provocation tests on two separate stimulation tests as defined as a serum peak GH concentration less than 10 ng/mL; and

e. Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypercortisolism).

2. Recertification Criteria:

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

b. Recipient has shown a beneficial response compared to pre-treatment baseline (with lonapegsomatropin-tcgd or somatropin [if used as switch maintenance]) as evidenced by greater than or equal to one of the following;

1. Improvement in height; or

2. Improvement in growth velocity.

3. Prior Authorization Guidelines:

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

G. Immediate-Release Fentanyl Products

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by the DUR Board: July 28, 2022~~July 25, 2013~~

Immediate-Release Fentanyl Products 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. Approval will be given if the following criteria are met and documented:

1. Subsys® (fentanyl sublingual spray), Onsolis® (fentanyl citrate buccal film), Fentora® (fentanyl citrate buccal tablet), Lazanda® (fentanyl citrate nasal spray), Abstral® (fentanyl citrate sublingual tablet) and Actiq® (fentanyl citrate transmucosal lozenge):

2. The recipient must meet all ~~of~~ the following:

~~1.~~a. The recipient is 18 years of age or older or the recipient is greater than 16 years of age if requesting fentanyl citrate transmucosal lozenge (Actiq®); and ~~The recipient is ≥ 18 years of age or ≥ 16 years of age if requesting fentanyl citrate transmucosal lozenge (Actiq®); and~~

b. ~~2.~~ The recipient has pain resulting from a malignancy; and

c. ~~3.~~ The recipient is already receiving and is tolerant to opioid therapy; and

d. ~~4.~~ The recipient is intolerant of at least ~~two~~ one of the following immediate-release opioids: hydrocodone, hydromorphone, morphine, or oxycodone.

b. Recertification Criteria:

1. Documentation of disease improvement and/or stabilization.

~~2.~~c. Prior Authorization Guidelines:

~~a.~~1. Prior authorization approval will be for six months.

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

I. Anti-Fungal ~~Onychomycosis~~Agents

Therapeutic Class: Antifungal Agents
Last Reviewed by the DUR: July 28, 2022~~September 3, 2015~~

Anti-Fungal ~~Onychomycosis~~ 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~~Topical Agents (Julia® (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.

~~Authorization will be given if the following criteria are met and documented:~~

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.

~~a. The agent is U.S. FDA approved for the treatment of onychomycosis (tinea unguium).~~

~~b. And one of the following:~~

~~1. The recipient is experiencing pain which limits normal activity; or~~

~~2. The recipient's disease is iatrogenically-induced; or~~

~~3. The recipient's disease is associated with immunosuppression; or~~

~~4. The recipient has diabetes; or~~

~~5. The recipient has significant peripheral vascular compromise.~~

~~c. And the requested length of therapy is appropriate, based on the agent and infection location.~~

~~d. And the drug and/or formulation-specific criteria is met:~~

~~1. Terbinafine: no pre-existing liver disease.~~

~~2. Itraconazole: The recipient does not have a diagnosis of heart failure and there is no evidence of ventricular dysfunction.~~

~~3. Oral granules dosage form: clinical rationale documenting why the recipient cannot or should not use terbinafine tablets or itraconazole capsules.~~

~~e. Topical dosage forms:~~

~~1. Inadequate response after an appropriate length of therapy with ciclopirox 8% solution or an adverse reaction or contraindication to ciclopirox 8% solution; and~~

~~2. Inadequate response after an appropriate length of therapy to either terbinafine tablets or itraconazole capsules or an adverse reaction or a contraindication to terbinafine tablets or itraconazole capsules or a clinical rationale why the recipient cannot use terbinafine tablets or itraconazole capsules.~~

~~f. Onmel (itraconazole) tablets: Clinical rationale documenting why the recipient cannot or should not use terbinafine tablets or itraconazole capsules.~~

~~2.~~b. Prior Authorization Guidelines

~~a.~~1. Prior authorization will be approved for 48 weeks.~~The extent of prior authorization approvals will be based on the appropriate use for the individual agents~~.

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

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.

K. Spinal Muscular Atrophy (SMA) Agents

Therapeutic Class: Spinal Muscular Atrophy Agents
Last Reviewed by the DUR Board: July 28, 2022~~January 28, 2021~~

SMA agents are subject to prior authorization and quantity limitatons based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid Check Up Pharmacy Manual for specific quantity limits.

1. Evrysdi® (risdiplam)

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

      1. Recipient has a diagnosis of SMA type I, II, or III; and

      2. Both the following:

         a. Recipient has mutation or deletion of genes in chromosome 5q resulting in one of the following:

            1. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); or

            2. Compound heterozygous mutation (e.g., deletion of survival motor neuron 1 (SMN1) exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

         b. Recipient has at least two copies of SMN2; and

      3. Recipient is not dependent on invasive ventilation or tracheostomy and non-invasive ventilation beyond use for naps and nighttime sleep; and

      ~~4. Recipient is at least two months of age or older; and~~

      4. ~~5.~~ At least one of the following exams (based on the recipient's age and motor ability) have been conducted to establish baseline motor ability:

         NOTE: Baseline assessments for patients less than two months of age requesting risdiplam proactively are not necessary to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

         a. Hammersmith Infant Neurological Exam (HINE) (infant to early childhood); or

         b. Hammersmith Functional Motor Scale Expanded (HFMSE); or

         c. Upper Limb Module (ULM) Test (Non ambulatory); or

d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND); or

e. Motor Function Measure 32 (MFM-32) Scale; and

5. ~~6.~~ The medication is prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA; and

6. ~~7.~~ Recipient is not to receive concomitant chronic SMN modifying therapy for the treatment of SMA (e.g. Spinraza®); and

7. ~~8.~~ One of the following:

a. Recipient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma®); or

b. Recipient has previously received gene therapy for the treatment of SMA (e.g. Zolgesma®) and the provider attest that there has been an inadequate response to gene therapy (e.g. sustained decrease in at least one motor test score over a period of six months).

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

1. The recipient has documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

a. One of the following HINE-2 milestones:

1. Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick; or

2. Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp; or

3. Recipient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement); or

4. The recipient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

b. One of the following HFMSE milestones:

1. Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

c. One of the following ULM test milestones:

1. Improvement or maintenance of a previous improvement of at least a 2-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

d. One of the following CHOP INTEND milestones:

1. Improvement or maintenance of a previous improvement of at least a 4-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); or

e. One of the following MFM-32 milestones:

1. Improvement or maintenance of a previous improvement of at least a 3-point increase in score from pretreatment baseline; or

2. Recipient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk); and

2. Recipient remains not be dependent on invasive ventilation or tracheostomy and use of non-invasive ventilation beyond use for naps and nighttime sleep; and

3. The medication is prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA; and

4. Recipient is not to receive concomitant chronic SMN modifying therapy for the treatment of SMA (e.g. Spinraza®); and

5. One of the following:

a. Recipient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma®); or

b. Recipient has previously received gene therapy for the treatment of SMA (e.g. Zolgesma®) and the provider attest that there has been an inadequate response to gene therapy (e.g. sustained decrease in at least one motor test score over a period of six months).

c. Prior Authorization Guidelines:

1. Initial authorization 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~~

2. Spinraza® (nusinersen)

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

1. Initial request:

a. The recipient has a diagnosis of SMA, and

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

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 is maintaining neurological status; and

c. The recipient is tolerating therapy; and

d. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA, 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 is maintaining neurological status; and

4. The recipient is tolerating therapy; and

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~~

3. Zolgensma® (onasemnogene abeparvovec-xioi)

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

1. The recipient must be two years of age or younger; and

a. The recipient must have the mutation or deletion of genes in chromosome 5q in one of the following: homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); or

b. Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1, exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

1. The recipient has a diagnosis of SMA confirmed by a neurologist with expertise in the diagnosis of SMA; or

2. The recipient has a diagnosis of SMA based on the results of SMA newborn screening with three copies or less of SMN 2; and

c. The recipient is not dependent on either invasive ventilation or tracheostomy or use of non-invasive ventilation beyond use of naps and nighttime sleep; and

d. Submission of medical records (e.g., chart notes, laboratory values) documenting the recipient's anti-AAV9 antibody titers are less than or equal to 1:50; and

e. The recipient is not to receive concomitant SMN modifying therapy (e.g. Spinraza®); and

f. The medication is prescribed by a neurologist with expertise in the diagnosis of SMA; and

g. The recipient has never received Zolgensma® treatment in their lifetime.

b. Prior Authorization Guidelines

1. Prior authorization approval is limited to once in a lifetime.

~~2. 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: July 28, 2022~~January 27, 2022~~

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:

      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.

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

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

      2. The agent is not for chronic use.

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

      4. Not recommended for use in immunocompromised patients.

   ~~b. Prior Authorization Guidelines:~~

      ~~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~~Recipient has had a trial and failure, contraindication, or intolerance to two or more of the following classes:

a. Prescription topical corticosteroids.

b. Topical calcineurin inhibitor (e.g., Elidel® (pimecrolims) or Protopic (tacrolimus)).

c. Topical phosphodiesterase-4 inhibitor (e.g., Eucrisa® (crisaborole)).

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

~~b. Topical prescription therapies are not advised for the patient~~

b. Recertification Request:

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

c. ~~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~~

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, 2022

Therapeutic Class: Ergot Derivitives
Last Reviewed by the DUR Board: July 28, 2022~~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.

2. Recertification Request:

a. The recipient must have a documented positive response to CGRP 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. 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:

a. The recipient has documented positive response to Emgality® therapy, demonstrated by a reduction in headache frequency and/or intensity; and

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

3. Prior Authorization Guidelines:

a. Initial request will be approved for three 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~~

3. CGRP's Antagonists for Episodic Migraines

a. Nurtec® ODT (rimegepant).

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

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

b. The recipient has a documented diagnosis of episodic migraines, having 4-18 migraine days per month but not more than 18 headache days per month; and

c. Two of the following:

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

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

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

b. Propranolol; or

c. Nadolol; or

d. Timolol; or

e. Metroprolol; and

d. Medication will not be used in combination with any other CGRP inhibitor.

2. Prior Authorization Guidelines:

a. Initial request will be approved for six months.

b. Recertification requests will be approved for 12 months.

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

4. Ergot Derivatives

a. Brand D.H.E. 45 (dihydroergotamine mesylate) injection, Generic dihydroergotamine mesylate injection, Brand Migranal nasal spray, or Generic dihydroergotamine mesylate nasal spray or Trudhesa®.

1. Approval will be given if all criterias are met and documented:

a. The recipient has a diagnosis of headahces with or without aura; and

b. The medication will be used for the acute treatment of migraine; and

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

d. One of the following:

1. The recipient has tried and failed or has intolerance to two triptants (e.g., eletriptan, rizatriptan, sumatriptan); or

2. The recipient has contraindication to all triptans; and

e. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist; and

f. If the recipient has more than four headache days per month, they must meet at least one of the following:

1. The recipient is currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications; or

2. The recipient is currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications; or

3. The recipient is currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications; and

2. Recertification Request:

a. The recipient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea); and

b. The medication is prescribed by or in consultation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. Prior Authorization Guidelines:

a. Initial request will be approved for three months.

b. Recertication requests will be approved for 12 months.

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

b. Brand D.H.E. 45 injection or Generic dihydroergotamine mesylate injection

1. Approval will be given if all criterias are met and documented:

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

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

   c. The recipient has had a trial and failure, contraindication, or intolerance to sumatriptain injection; and

   d. The medication is prescrived by or in consulation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

2. Recertification Request:

   a. The recipient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity; and

   b. The medication is prescrived by or in consulation with either a Neurologist, a Pain Specialist, or a Headache Specialist.

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification requests will be approved for three months.

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

CC. Multiple Sclerosis (MS) Agents

Therapeutic Class: Agents for the treatment of Neuromuscular Transmission Disorder
Last Reviewed by the DUR Board: July 28, 2022~~April 22, 2021~~

MS 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. The recipient has a diagnosis of MS.

2. Ampyra® (dalfampridine)

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

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

      2. The medication is being used to improve the recipient's walking speed; and

      3. The medication is being prescribed by or in consultation with a neurologist; and

      4. The recipient is ambulatory and has an EDSS score between 2.5 and 6.5; and

      5. The recipient does not have moderate to severe renal dysfunction (CrCL less than 50 ml/min); and

      6. The recipient does not have a history of seizures; and

      7. The recipient is not currently pregnant or attempting to conceive.

   b. Prior Authorization Guidelines

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

      2. Request for continuation of therapy will be approved for one year.

3. Relapsing Forms of MS Agents:

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

      1. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses).

   b. Lemtrada® (alemtuzumab)

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

    a. The recipient must have a diagnosis of a relapsing form of MS; and one of the following:

        1. Both the following:

            a. The recipient has not been previously treated with alemtuzumab; and

            b. The recipient has had failure after a trial of at least four weeks; a contraindication, or intolerance to two of the following disease-modifying therapies for MS:

                1. Aubagio (teriflunomide)
                2. Avonex® (interferon beta-1a)
                3. Betaseron® (interferon beta-1b)
                4. Copaxone/Glatopa® (glatiramer acetate)
                5. Extavia (interferon beta-1b)
                6. Gilenya® (fingolimod)
                7. Mavenclad (cladrivine)
                8. Mayzent® (siponimod)
                9. Ocrevus (ocrelizumab)
                10. Plegridy® (peginterferon beta-1a)
                11. Rebif (interferon beta-1a)
                12. Tecfidera (dimethyl fumarate)
                13. Tysabri (natalizumab); or
                14. Zinbryta (daclizumab)

        c. Both the following:

            a. The recipient has previously received treatment with alemtuzumab; and

            b. The recipient has had at least 12 months elapsed or will have elapsed since the most

recent treatment course with alemtuzumab; and

2. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Initial authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

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

c. Mavenclad® (cladribine)

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

a. The recipient must have a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and one of the following:

1. Both the following:

a. The recipient has not been previously treated with cladribine; and

b. The recipient has had failure after a trial of at least four weeks; contraindication, or intolerance to two of the following disease-modifying therapies for MS:

1. Aubagio (teriflunomide)

2. Avonex® (interferon beta-1a)

3. Betaseron® (interferon beta-1b)

4. Copaxone®/Glatopa® (glatiramer acetate)

5. Extavia (interferon beta-1b)

6. Gilenya® (fingolimod)

7. Lemtrada® (alemtuzumab)

8. Mayzent® (siponimod)

9. Ocrevus (ocrelizumab)

10. Plegridy® (peginterferon beta-1a)

11. Rebif (interferon beta-1a)

12. Tecfidera (dimethyl fumarate)

13. Tysabri (natalizumab); or

14. Zinbryta (daclizumab)

2. Both the following:

a. The recipient has previously received treatment with cladribine; and

b. The recipient has not already received the FDA-recommended lifetime limit of two treatment courses (or four treatment cycles total) of cladribine; and

b. The medication will not be used in combination with another disease-modifying therapy for MS.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for one month.

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

d. Ocrevus® (ocrelizumab)

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

a. The recipient has a diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

3. Prior Authorization Guidelines

a. Initial prior authorization approval will be 12 months.

b. Recertification approval will be for 12 months.

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

e. Zeposia® (ozanimod)

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

a. The recipient has a documented diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); and

b. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

a. Avonex® (interferon beta-1a)

b. Betaseron® (interferon beta-1b)

c. Copaxone®/Glatopa® (glatiramer acetate)

d. Tecfidera (dimethyl fumarate); and

c. The medication is prescribed by or in consultation with a neurologist.

2. Recertification Criteria (the recipient must meet all criteria):

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. The medication is prescribed by or in consultation with a neurologist.

3. Prior Authorization Guidelines:

a. Prior authorization approval will be for 12 months.

b. Recertification approval will be for 12 months.

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

f. Ponvory® (ponesimod)

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

a. Recipient has a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease [RRMS]; active secondary progressive MS [SPMS]+, or clinically isolated syndrome [CIS]); and

b. Recipient will NOT be initiating therapy after previous treatment with alemtuzumab; and

c. Ponesimod will be prescribed by, or in consultation with, neurologist; and

d. One of the following:

1. The agent is used for continuation of therapy; or

2. The recipient has had failure after a trial of at least four weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS;

a. Avonex® (interferon beta-1a); or

b. Betaserone® (interferon beta-1b); or

c. Copaxone®/Glatopa® (glatiramer acetate); or

d. Tysabri® (natalizumab); or

e. Tefidera® (dimethyl fumarate); or

f. Aubagio® (teriflunomide); or

g. Gilenya® (fingolimod)

2. Recertification Request:

a. The recipient has documentation of positive clinical response to therapy (e.g., improvement in radiologic disease activity, clinical relapses, disease progression); and

b. Ponesimod will be prescribed by, or in consultation with, neurologist.

3. Prior Authorization Guidelines:

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

4. Primary Progressive Forms of Multiple Sclerosis (PPMS) Agents:

a. Ocrevus® (ocrelizumab)

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

a. The recipient must have a diagnosis of PPMS; and

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

c. The medication must not be used in combination with another B-cell targeted therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

d. The medication must not be used in combination with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

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

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

b. The medication must not be used in combination with another disease-modifying therapy for MS; and

3. ~~c.~~ The medication must not be used in combination with another B-cell target therapy (e.g., Rituxan® (rituximab), Benlysta (belimumab), Arzerra (ofatumumab)); and

   ~~d.~~a. The medication must not be used with another lymphocyte trafficking blocker (e.g., Lemtrada® (alemtuzumab), mitoxantrone).

~~3.~~4. Prior Authorization Guidelines

   a. Prior authorization approval will be for 12 months.

   b. Recertification approval will be for 12 months.

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

ZZ. Human Immunodeficiency Virus (HIV) Agents

Therapeutic Drug Class: HIV Agents
Last Reviewed by the DUR Board: ~~January 27, 2022~~April 28, 2022

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

         ~~f~~e. 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~~

FFF. Antipsychotic Drugs: Atypical ~~Invega Trinza® (paliperidone palmitate)~~

Therapeutic Class: Second Generation (Atypical) Antipsychotic
Last Reviewed by the DUR Board: July 28, 2022~~November 5, 2015~~

Atypical Antipsychotic Drugs ~~Trinza® (paliperidone palmitate) 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. Invega Trinza® (paliperidone palmitate)~~Coverage and Limitations~~

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

      ~~a.~~1. The recipient has a diagnosis of schizophrenia; and

      2. ~~b.~~ The recipient has been stabilized on once-monthly paliperidone palmitrate injection (Invega Sustenna®) for at least four months with the two most recent doses of the once-monthly injection being the same strength; and

      3. ~~c.~~ The recipient is 18 years of age or older; and

      4. ~~d.~~ The requested dose is one injection every three months.

   ~~3.~~b. ~~2.~~ Prior Authorization Guidelines

      ~~a.~~1. Prior authorization approvals will be for one year.

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

2. Invega Hafyera® (paliperidone palmitate)

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

      1. The recipient has a diagnosis of schizophrenia; and

      2. The recipient has been stabilized on once-monthly palperidone palmitrate extended-release (PP1M) injectable suspension (Invega Sustenna®) for at least four months, the two most recent doses of the once-monthly injection being the same strength or one dose of three-month IM paliperidone (Inevga Trinza®); and

      3. Patient is 18 years of age or older; and

      4. The requested dose is one injection every six months

b. Recertification Requests:

1. Recipient must have a positive response from therapy.

c. Prior Authorization Guidelines:

1. Prior authorization approvals will be for one year.

HHH. Ileal Bile Acid Transporter (IBAT) Inhibitor (D7F)) ~~(RESERVED FOR FUTURE USE)~~

Therapeutic Drug Class: Ileal bile acid transporter (IBAT) inhibitor (D7F)
Last Reviewed by the DUR Board: July 28, 2022

Ileal bile acid transporter (IBAT) inhibitor (D7F) 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. Bylvay® (odevixibat)

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

      1. Recipient is three months of age or older; and

      2. Recipient is diagnosed with progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; and

      3. Recipient has elevated serum bile acid concentration; and

      4. Recipient experiences persistent moderate to severe pruritus; and

      5. Recipient does not have any of the following;

         a. Positive test for the ABCB11 gene variant that predicts complete absence of the bile salt export pump (BSEP) protein; and

         b. Prior heaptic decompensation event; and

         c. Another concomitant liver disease; and

         d. An international normalized ratio (INR) greater than 1.4; and

         e. Significant portal hypertension; and

         f. An alanine aminotransferase (ALT) or total bilirubin (TB) level more than 10 times the upper limit of normal (ULN); and

         g. Medical history or ongoing chronic diarrhea; and

         h. Decompensated cirrhosis; and

         i. Significant portal hypertension; and

      6. Bylvay® is prescribed by or in consultation with a specialist (e.g. gastroenterologist, hepatologist, dermatologist).

b. Recertification Request:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite vitamin A,D,E,K supplementation; elevated liver function tests [alanine aminotransferase (ALT), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension

c. Prior Authorization Guidelines:

1. Prior authorization approval will be given for 12 months

2. Livmarli® (maralixibat)

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

1. Recipient is one year of age or older; and

2. Recipient is diagnosed with Alagille syndrome; and

3. Recipient experiences persistent moderate to severe pruritus; and

4. Recipient does not have any of the following;

a. Chronic diarrhea requiring ongoing intravenous fluid or nutritional intervention; and

b. Prior hepatic decompensation event; and

c. Significant portal hypertension; and

d. Decompensated cirrhosis; and

e. Another concomitant liver disease; and

5. Maralixibat is prescribed by or in consultation with a specialist (e.g.,gastroenterologist, hepatologist, dermatologist); and

6. Patient has failed an adequate trial, or is intolerant to, or has a contraindication to at least one pruritus treatment (e.g., ursodeoxycholic acid [ursodiol], cholestyramine, rifampin, naloxone, naltrexone, antihistamine).

b. Recertification Request:

1. Recipient has experienced a reduction in serum bile acids from baseline; and

2. Recipient must continue to meet the above criteria, except for the initial serum bile acid approval criteria; and

3. Recipient must experience improvement in pruritus; and

4. Recipient has not experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin defiency despite Vitamin A, D, E, K supplementation; elevated liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TB), direct bilirubin (DB)]); and

5. Recipient has not developed decompensated cirrhosis; and

6. Recipient has not developed significant portal hypertension.

c. Prior Authorization Guidelines:

1. Prior Authorization approval will be given for six months.

2. Recertification will be given for 12 months.