MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

June 29, 2021

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: JESSICA KEMMERER, HIPAA PRIVACY AND CIVIL RIGHTS OFFICER

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 January 28, 2021 by the Drug Use Review (DUR) Board. The proposed changes include: Addition of new prior authorization criteria for Evrysdi® (risdiplam) within the new combined Spinal Muscular Atrophy (SMA) Agents section; addition of new prior authorization criteria for Vyondys 53® (golodirsen) within the new combined Duchenne Muscular Dystrophy (DMD) Agents section; Addition of new prior authorization criteria for Qutenza® (capsaicin); new prior authorization criteria for Fintepla® (fenfluramine) and lastly, technical changes to the Immunomodulator Drugs section to correct grammatical and inaccurate information.

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

These changes are effective July 5, 2021.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED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

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section K.	**Zolgenma® (onasemnogene abeparvovec xioi)**	Revised section title to "Spinal Muscular Atrophy (SMA) Agents." Revised last reviewed date. Added new clinical prior authorization criteria for Evrysdi® (risdiplam). Relocated clinical prior authorization criteria for Spinraza® (nusinersen) within this section. Removed type I and type II from the current

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		Zolgensma prior authorization criteria to follow previously approved criteria by the DUR Board.
Appendix A Section L.	**Immunomodulator Drugs**	Revised and removed the use of symbols throughout the section to improve readability. Corrected grammatical errors throughout section and broken web links.
Appendix A Section MMM.	**Exondys 51® (eteplirsen)**	Revised section title to "Duchenne Muscular Dystrophy (DMD) Agents." Revised last reviewed date. Relocated clinical prior authorization criteria for Emflaza® (deflazacort) within section. Added new prior authorization criteria for Vyondys 53® (golodirsen).
Appendix A Section NNN.	**Spinraza® (nusinersen)**	Revised section title to "Qutenza® (capsaicin)." Revised last reviewed date. Relocated current Spinraza® (nusinersen) within section K. Added new clinical prior authorization criteria for Qutenza® (capsaicin).
Appendix A Section RRR.	**Emflaza® (deflazacort)**	Relocated current clinical prior authorization criteria for Emflaza® (deflazacort) within section MMM. Revised section title to "RESERVED FOR FUTURE USE.
Appendix A Section BBBB.	**Anticonvulsants**	Revised last reviewed date. Revised broken web links. Added new clinical prior authorization criteria for Fintepla® (fenfluramine).

K. Spinal Muscular Atrophy (SMA) Agents~~Zolgensma (onasemnogene abeparvovec-xioi)~~

Therapeutic Class: Spinal Muscular Atrophy Agents
Last Reviewed by the DUR Board: January 28, 2021~~October 17, 2019~~

SMA agents are ~~Zolgensma® (onasemnogene abeparvovec-xioi) is~~ 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)~~Coverage and Limitations~~

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

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

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

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

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:

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

2. 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 ~~Spinal Muscular Atrophy (~~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 ~~of~~ the following:

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

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

3. The recipient is maintaining neurological status; and

4. The recipient is tolerating therapy; and

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

3. Prior Authorization Guidelines

a. Initial request will be approved for 12 months. ~~Prior authorization approvals will be for:~~

~~Initial request: 12 months.~~

b. Recertification request~~:~~ will be approved for 12 months.~~continued use shall be reviewed at least every 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. ~~a.~~ The recipient must be two years of age or younger; and

a. ~~1.~~ 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. ~~2.~~ Compound heterozygous ~~hetereozygous~~ mutation of ~~Survival of Motor Neuron 1 (~~SMN1~~)~~ gene (e.g., deletion of SMN1, exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

1. ~~a.~~ The recipient has a diagnosis of ~~symptomatic Type I or Type II~~ SMA confirmed by a neurologist with expertise in the diagnosis of SMA; or

2. ~~b.~~ The recipient has a diagnosis of SMA based on the results of SMA newborn screening with three copies or less of ~~Survival of Motor Neuron 2 (~~SMN 2~~)~~; and

c. ~~3~~. 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. ~~4.~~ 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. ~~5.~~ The recipient is not to receive concomitant SMN modifying therapy (e.g. Spinraza®); and

f. ~~6.~~ The medication is prescribed by a neurologist with expertise in the diagnosis of SMA; and

g. ~~7.~~ The recipient has never received Zolgensma® treatment in their lifetime.

b. ~~2.~~ Prior Authorization Guidelines

1. Prior authorization approval~~s will be for a one time authorization in lifetime~~is limited to once in a lifetime..

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

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: October 18, 2018

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)	Stelara® (ustekinumab)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Taltz® (ixekizumab)
Humira® (adalimumab)	Otezla® (apremilast)	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. Coverage and Limitations

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. 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.

a. 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.

b. 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~~sulfasalzine~~, leflunomide, minocycline).

c. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

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

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

a. Abatacept: Six years of age or older

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

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

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

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

d. Plaque Psoriasis:

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

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

3. The agent is prescribed by a dermatologist; and

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

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

g. Crohn's Disease:

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

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

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

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

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

4. The recipient has fistulizing Crohn's Disease.

h. Ulcerative Colitis:

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

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

a. Infliximab: Six years of age or older.

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

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

a. Corticosteroids;

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

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

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

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

a. Canakinumab: Four years of age or older.

b. Rilonacept: 12 years of age or older.

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

1. The recipient has a diagnosis of NOMID.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for 12 months.

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

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

~~Prior authorization approval will be for one year.~~

MMM. ~~Exondys 51® (eteplirsen)~~ Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
~~Exondys 51® (eteplirsen)~~
Last Reviewed by the DUR Board: ~~August 24, 2017~~ January 28, 2021

DMD agents are ~~Exondys 51® (eteplirsen) 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.

~~3.~~a. Exondys 51® (eteplirsen) ~~Coverage and Limitations~~

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

1. Initial request:

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

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

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

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

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

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

b. The recipient has experienced clinically significant benefit; and

c. The recipient is tolerating therapy; and

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

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

~~3.~~1. The recipient has been on therapy for 12 months or more; and

~~4.~~2. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and

~~5.~~3. The recipient has experienced clinically significant benefit; and

~~1.~~4. The recipient is tolerating therapy; and

~~6.~~5. The prescribed dose will not exceed 30 milligrams per kilogram of body weight once weekly; and

~~7.~~6. The medication is prescribed by or in consultation with a neurologist who has experience treating children.

~~4.~~b. Prior Authorization Guidelines

~~3.~~1. ~~Prior authorization approvals will be for:~~ Initial authorization will be approved for six months.

~~1.~~2. Recertification request will be approved for 12 months.~~Initial request: six months.~~

~~2. Recertification request: one year.~~

~~4.~~3. Prior Authorization forms are available at: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx ~~http://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

2. Emflaza® (deflazacort)

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

a. Initial request:

1. The recipient must have a diagnosis of ~~Duchenne muscular dystrophy~~ (DMD); and

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

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

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

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

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

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

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

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

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

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

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

c. Prior Authorization Guidelines

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

2. Recertification request will be approved for 12 months.

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

3. Vyondys 53® (golodirsen)

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

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

   a. The recipient has a diagnosis of DMD; and

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

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

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

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

1. One of the following:

   a. All the following:

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

      2. The recipient is tolerating therapy; and

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

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

   b. All the following:

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

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

      3. Recipient is tolerating therapy; and

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

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

c. Prior Authorization Guidelines:

   1. Initial authorization will be approved for six months.

   2. Recertification request will be approved for 12 months.

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

NNN. Qutenza® (capsaicin)~~Spinraza® (nusinersen)~~

Therapeutic Class: Topical Neuropathic Pain Agents~~Spinraza® (nusinersen)~~
Last Reviewed by the DUR Board: January 28, 2021~~August 24, 2017~~

Qutenza® (capsaicin)~~Spinraza® (nusinersen)~~ 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:~~

~~1. Initial request:~~

~~a. The recipient has a diagnosis of Spinal Muscular Atrophy (SMA), and~~

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

~~2.1. Recertification Request (the recipient must meet all the following criteria):~~

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

~~b.a. The recipient is maintaining neurological status; and~~

~~c.a. The recipient is tolerating therapy; and~~

~~d.a. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA, or all of the following:~~

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

~~2.1. The recipient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients); and~~

~~3.1. The recipient is maintaining neurological status; and~~

~~4.1. The recipient is tolerating therapy; and~~

~~5.1. The medication is prescribed by or in consultation with a neurologist who has experience treating SMA.~~

~~2.1. Prior Authorization Guidelines~~

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

~~a. Initial request: 12 months.~~

~~b.a. Recertification request: continued use shall be reviewed at least every 12 months.~~

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

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

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

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

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

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

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

3. Prior Authorization Guidelines:

   a. Initial authorization will be approved for three months.

   b. Recertification request will be approved for three months.

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

RRR. ~~Emflaza® (deflazacort)~~ RESERVED FOR FUTURE USE

~~Therapeutic Class: Emflaza® (deflazacort)~~
~~Last Reviewed by the DUR Board: October 19, 2017~~

~~Emflaza® (deflazacort) 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.~~

~~a. Coverage and Limitations~~

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

~~a. Initial request:~~

~~1. The recipient must have a diagnosis of Duchenne muscular dystrophy (DMD); and~~

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

~~3. The recipient must have received genetic testing for a mutation of the dystrophin gene, and one of the following:~~

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

~~b. Muscle biopsy confirming an absence of dystrophin protein; and~~

~~4. The medication must be prescribed by or in consultation with a neurologist who has experience treating children; and~~

~~5. The recipient has had at least a three month trial and failure of prednisone (prednisolone or equivalent dose) or a documented intolerance to prednisone (prednisolone or equivalent dose) given at a dose of 0.75 mg/kg/day or 10 mg/kg/week; and~~

~~6. The dose will not exceed 0.9 milligrams per kilogram of body weight once daily.~~

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

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

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

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

~~c. Prior Authorization Guidelines~~

~~3. Initial prior authorization approval will be for 12 months.~~

~~4. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx~~

BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants
Last Reviewed by the DUR Board: January 28, 2021~~July 23, 2020~~

Anticonvulsants 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. Cannabinoid

   a. Epidiolex® (cannabidiol)

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

         a. The recipient has a diagnosis of Lennox-Gastaut syndrome, Dravet Syndrome or Tuberous Sclerosis Complex (TSC); and

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

         c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and

         d. The drug is prescribed by or in consultation with a neurologist; and

         e. The total dose does not exceed 20 mg/kg/day (10mg/kg twice daily); and

         f. The medication will be used as adjunctive therapy (the recipient has been taking one or more antiepileptic drugs and has chart notes confirming the presence of at least four convulsive seizures per month).

   2. Recertification Request

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

      b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.

   3. Prior Authorization Guidelines

      a. Initial prior authorization will be for three 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

4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.

2. Nayzilam® (midazolam)

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

1. The recipient has a diagnosis of acute intermittent seizures; and

2. The recipient is at least 12 years of age; and

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

4. The dose must not exceed two sprays per seizure cluster, no more than one episode every three days and treat no more than five episodes per month.

b. Recertification Request

1. Documentation of positive clinical response to Nayzilam® therapy.

c. Prior Authorization Guidelines

1. Initial prior authorization will be for six months.

2. Recertification approval will be for 12 months.

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

3. Valtoco® (diazepam)

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

1. The recipient has a diagnosis of epilepsy; and

2. The recipient is six years and older; and

3. The medication is prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern; and

4. The prescriber documents a reason or special circumstance that precludes the use of diazepam rectal gel; and

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

6. The quantity must not exceed five episodes per month.

b. Prior Authorization Guidelines:

1. Documentation of positive clinical response to Valtoco® therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification approval will be approved for 12 months.

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

4. Fintepla® (fenfluramine)

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

1. The recipient has a documented diagnosis of seizures associated with Dravet Syndrome; and

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

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

b. Recertification Request:

1. The recipient has documentation of positive clinical response to Fintepla® therapy.

c. Prior Authorization Guidelines:

1. Initial authorization will be for 12 months.

2. Recertification approval will be for 12 months.

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