Medicaid Services Manual
Transmittal Letter

January 30, 2023

To: Custodians of Medicaid Services Manual

From: Casey Angres
Chief of Division Compliance

Subject: Medicaid Services Manual Changes
Chapter 1200 – Prescribed Drugs

Background And Explanation

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs are being proposed to reflect recommendations approved on October 19, 2023, by the Drug Utilization Review (DUR) Board meeting. The addition of Spevigo® (spesolimab-sbzo) under Immunomodulator Drugs, including updated PA guidelines. Under Section MMM – Duchenne Muscular dystrophy (DMD) Agents, Elevidys™ (Delandistrogene Moxeparvovec-Rokl) was added and under Section GGGG – Relyvrio® (sodium phenylbutyrate/taurursodiol) Qalsody™ (Tofersen) was added. Vyjuvek™ (beremagene geperpavec-svdt) has been added to new Section KKKK. Section LLLL to Section SSSS have been added for the following new drugs: Hemgenix® (etranacogene dezaparvovec-drlb), Roctavian™ (valoctocogene roxaparvovec-rvox), Evkeeza™ (evinacumab-dgnb), Joenja® (leniolisib), Daybue™ (trofinetide), Elfabrio® (pegunigalsidase alfa-iwxj), Xiaflex® (collagenase clostridium histolyticum) and Skyclarys® (omaveloxolone).

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

These changes are effective February 5, 2024.

Material Transmitted	Material Superseded
MTL NA MSM 1200 Prescribed Drugs	MTL NA MSM 1200 Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section L	**Immunomodulator Drugs**	Updated last review date. Added Spevigo® (spesolimab-sbzo). Updated PA Guidelines.

Appendix A Section MMM	**Duchenne Muscular Dystrophy (DMD) Agents**	Updated last review date. Added Elevidys™ (Delandistrogene Moxeparvovec-Rokl).
Appendix A Section GGGG	**Relyvrio® (sodium phenylbutyrate/ taurursodiol**	Updated last review date. Added Qalsody™ (Tolfersen).
Appendix A Section KKKK	**Vyjuvek™ (beremagene geperpavec-svdt)**	Created new section for Vyjuvek™ including prescription, prior authorization criteria and quantity limits.
Appendix A Section LLLL	**Hemgenix® (etranacogene dezaparvovec-drlb)**	Created new section for Hemgenix® including prescription, prior authorization criteria and quantity limits.
Appendix A Section MMMM	**Roctavian™ (valoctocogene roxaparvovec-rvox**	Created new section for Roctavian™ including prescription, prior authorization criteria and quantity limits.
Appendix A Section NNNN	**Evkeeza™ (evinacumab-dgnb)**	Created new section for Evkeeza™ including prescription, prior authorization criteria and quantity limits.
Appendix A Section OOOO	**Joenja® (Leniolisib)**	Created new section for Joenja® including prescription, prior authorization criteria and quantity limits.
Appendix A Section PPPP	**Daybue™ (trofinetide)**	Created new section for Daybue™ including prescription, prior authorization criteria and quantity limits.
Appendix A Section QQQQ	**Elfabrio® (pegunigalsidase alfa-iwxj)**	Created new section for Elfabrio® including prescription, prior authorization criteria and quantity limits.
Appendix A Section RRRR	**Xiaflex® (collagenase clostridium histolyticum)**	Created new section for Xiaflex® including prescription, prior authorization criteria and quantity limits.
Appendix A Section SSSS	**Skyclarys®**	Created new section for Skyclarys® including prescription, prior authorization criteria and quantity limits.

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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 add Continuous Glucose Monitors for recipients with Diabetes Mellitus II.

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.

Entities Financially Affected: This proposed change affects all Medicaid-enrolled providers delivering Diabetic Supply type of services. Those provider types (PT) include but are not limited to: Pharmacy (PT 28), Inpatient Hospitals (PT 11), Outpatient Hospitals (PT 12), Nursing Facilities (PT 19), DMEPOS (PT 33), and Indian Health Services and Tribal Clinics (PT 47).

Financial Impact on Local Government: Fiscal Savings to Division of Healthcare Financing and Policy (DHCFP).

These changes are effective February 5, 2024.

Material Transmitted	Material Superseded
MTL NA MSM 1200 Prescribed Drugs	MTL NA MSM 1200 Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
MSM 1200, Appendix B4	**DIABETIC SUPPLY PROGRAM**	Links updated for forms and preferred product list. Added coverage for Continuous Glucose Monitors for recipients with Diabetes Mellitus II.

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: October 19, 2023~~July 27, 2023~~

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

Immunomodulator Drugs are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

   a. For all recipients:

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

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

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

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

      5. Each request meets the appropriate diagnosis/agent specific criteria (b-k).

   b. Rheumatoid Arthritis (RA):

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

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

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

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

disease modifying antirheumatic drug (DMARD) (methotrexate, hydroxychloroquine, leflunomide, minocycline and sulfasalazine); or

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

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

c. Psoriatic Arthritis:

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

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

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

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

d. Ankylosing Spondylitis:

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

2. The recipient is 18 years or older; and

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

e. Juvenile Rheumatoid Arthritis/Juvenile Idiopathic Arthritis:

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

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

a. Abatacept: Six years of age or older.

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

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.

f. Plaque Psoriasis:

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

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

3. The agent is prescribed by a dermatologist; and

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

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

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, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine, leflunomide); or

4. The recipient has fistulizing Crohn's Disease.

h. Ulcerative Colitis (UC):

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

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

a. Infliximab: Six years of age or older.

b. Humira: five years of age or older.

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

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

b. 5-aminosalicylic acid agents;

c. Immunosuppressants; and/or

d. Thiopurines.

4. Zeposia® (ozanimod) for diagnosis of UC

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

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

2. The ~~R~~recipient has a diagnosis of moderately to severely active UC; and

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

a. 6-mercaptopurine

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

c. Sulfasalzine

d. Azathioprine

e. Corticosteroids (e.g., budesonide, high dose steroids 40-60mg of prednisone daily); and

4. The ~~R~~recipient has tried and failed two preferred immunomodulator therapies indicated for moderately to severely active UC.

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.

k. Remicade biosimilars (infliximab-axxq, infliximab-abda, infliximab-dyyb, infliximab-qbtx).

1. Medication prescribed for FDA-approved diagnosis and patient is appropriate age per FDA labeling.

2. Prescriber has provided documentation to justify that patient is not a candidate for unbranded/generic Infliximab (e.g. product-specific past intolerance or contraindication).

l. Spevigo® (spesolimag-sbzo) for generalized pustular psoriasis (GPP) flares.

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

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

b. Diagnosis of generalized pustular psoriasis (GPP); and

c. Prescribed by or in consultation with a dermatologist, immunologist, or rheumatologist; and

d. The recipient does not have any of the following conditions: synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome; erythrodermic plaque psoriasis without pustules or with pustules restricted to psoriatic plaques, or drug-triggered AGEP (acute generalized exanthematous pustulosis); and

e. The recipient is experiencing an acute GPP flare of moderate to severe intensity defined by all the following: Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 (moderate), presence of fresh pustules (new or worsening) a GPPGA pustulation of sub score of ≥ 2 (mild), and ≥ 5% of body surface area with erythema and the presence of pustules; and

f. The recipient has not received a live virus vaccine in the last four weeks and will not receive a live virus vaccine during therapy.

2. PA approval will be 14 days.

2. PA Guidelines:

a. PA approval will be for 12 months unless other stated in criteria.

b. PA forms are available at:

c. https://nevadamedicaid.magellanrx.com/provider/forms.

MMM. Duchenne Muscular Dystrophy (DMD) Agents

Therapeutic Class: Duchenne Muscular Dystrophy (DMD) Agents
Last Reviewed by the DUR Board: October 19, 2023~~January 27, 2022~~

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

1. Exondys 51® (eteplirsen)

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

      1. Initial request:

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

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

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

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

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

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

         b. The recipient has experienced clinically significant benefit; and

         c. The recipient is tolerating therapy; and

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

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

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

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

            3. The recipient has experienced clinically significant benefit; and

4. The recipient is tolerating therapy; and

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

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

b. Prior Authorization Guidelines

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

2. Emflaza® (deflazacort)

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

1. Initial request:

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

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

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

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

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

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

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

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

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

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

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

c. Prior Authorization Guidelines:

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

2. Recertification request will be approved for 12 months.

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

3. Vyondys 53® (golodirsen)

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

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

a. The recipient has a diagnosis of DMD; and

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

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

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

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

1. One of the following:

a. All the following:

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

2. The recipient is tolerating therapy; and

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

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

b. All the following:

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

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

3. The ~~R~~recipient is tolerating therapy; and

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

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

4. Viltepso® (viltolarsen)

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

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

a. The recipient has a diagnosis of DMD; and

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

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

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

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

1. One of the following:

a. All of the following:

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

2. The recipient is tolerating therapy; and

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

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

b. All of the following:

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

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

3. The recipient is tolerating therapy; and

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

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

c. Prior Authorization Guidelines:

1. Initial authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

5. Amondys 45® (casimersen)

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

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

a. Diagnosis of Dystrophy (DMD); and

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

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

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

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

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

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

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

c. Prior Authorization Guidelines:

1. Prior authorization will be approved for six months.

2. Recertification request will be approved for 12 months.

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

6. Elevidys™ (Delandistrogene Moxeparvovec-Rokl)

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. The recipient has confirmed mutation of the DMD gene between exons 1 to 71; and

c. The recipient does not have any deletion in exon 8 and/or exon 9 in the DMD gene; and

d. The recipient must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by ELISA.

2. Age four through five years old; and

3. Prescribed by or in consultation with pediatric neuromuscular specialist with advanced knowledge in treating DMD; and

4. The recipient is ambulatory as confirmed by prescriber attestation; and

5. The recipient is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen); and

6. The recipient does not have an active infection, including clinically important localized infections; and

7. The recipient has been on a stable dose of corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); and

8. The recipient's troponin-I levels will be monitored at baseline and subsequently as clinically indicated; and

9. The recipient will have liver function assessed prior to and following therapy for at least three months as indicated; and

10. The recipient is receiving physical and/or occupational therapy; and

11. The recipient has never previously received Elevidys treatment in their lifetime.

b. Recertification requests:

1. Coverage not renewable.

GGGG. Relyvrio® (sodium phenylbutyrate/taurursodiol)

Therapeutic Class: Amyotrophic Lateral Sclerosis (ALS)
Last reviewed by DUR Board: ~~January~~ October 19, 2023

Relvyrio® (sodium phenylbutyrate/taurursodiol) 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. Relyvrio® (sodium phenylbutyrate/taurursodiol)

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

      1. The ~~R~~recipient is greater than or equal to 18 years of age; and

      2. The ~~R~~recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

      3. The ~~R~~recipient must have an adequate trial of riluzole for greater than or equal to eight weeks or contraindication to therapy; and

      4. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R); and

      5. The ~~R~~recipient does not require permanent assisted ventilation; and

      6. Therapy prescribed by or in consultation with neurologist; and

   b. Recertification Request:

      1. The ~~R~~recipient must continue to meet the above criteria; and

      2. The ~~R~~recipient must have disease stabilization or improvement in the slope of decline as demonstrated on an objective measure/tool (e.g., ALSFRS-R); and

      3. The ~~R~~recipient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure).

   a. Prior Authorization Guidelines:

      1. Initial approval will be given for six months.

      2. Recertification will be approved for six months.

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

2. Qalsody™ (Tofersen)

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

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

2. The recipient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); and

3. The recipient has a baseline measure of plasma neurofilament light chain (NfL) and

4. Prescribed by or in consultation with a neurologist; and

5. The recipient has the presence of a superoxide dismutase 1 (SOD1) gene mutation; and

6. Dosing is in accordance with FDA approved labeling.

B. Recertification Request:

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

2. The recipient must have stabilization or improvement in plasma NfL compared to baseline; and

4. The recipient has responded to therapy compared to pretreatment baseline with disease stability or mild progression (recipient has not experienced rapid disease progression while on therapy); and

5. Dosing is in accordance with FDA approved labeling.

C. Prior Authorization Guidelines:

1. Initial approval will be given for 12 months.

2. Recertification will be approved for 12 months.

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

HHHH. Verkazia® (cyclosporine)

Therapeutic Class: Ophthalmic Anti-Inflammatory Agents
Last Reviewed by DUR Board: April 20, 2023

Verkazia® (cyclosporine) are subject to PA and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

    a. Recipient is greater than or equal to four years old; and

    b. Recipient has a diagnosis of vernal keratoconjunctivitis; and

    c. Prescriber attestation that disease severity is moderate to severe; and

    d. Recipient has had a disease flare within the past one year; and

    e. Recipient is not using another immunomodulator via the ophthalmic route (e.g., other formulations of cyclosporine, tacrolimus, pimecrolimus).

2. Dosage Limits

    a. Max daily dose of four vials

3. Recertification Requests:

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

    b. Prescriber attestation that recipient has had disease improvement and/or stabilization (e.g., improvement on corneal fluorescein staining [CFS], decrease in number of flares, improvement in symptoms); and

    c. Recipient has not experienced any treatment-restricting adverse effects (e.g., eye pain, infection).

4. Prior Authorization Guidelines:

    a. Initial approval will be given for 12 months.

    b. Recertification will be given for 12 months.

IIII. Strensiq® (asfotase alfa)

Therapeutic Class: Hypophosphatasia (HPP) Agents
Last Reviewed by DUR Board: July 27, 2023

HPP are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

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

   A recipient has a diagnosis of either perinatal/infantile or juvenile-onset HPP demonstrated by all of the following:

   a. The recipient was 18 years of age or younger at onset;

   b. The recipient experienced clinical manifestations of HPP (e.g., vitamin B6-responsive seizures, chest deformity, severe hypercalcemia, bowing of the long bones, failure to thrive);

   c. The recipient obtained radiographic imaging to support diagnosis of HPP;

   d. Genetic testing has been completed documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation; and

   e. There has been reduced activity of unfractionated serum alkaline phosphatase (ALP);

   f. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

   g. The requested quantity is within FDA-labeled dosing requirement based on the recipient's weight.

2. Recertification request:

   a. Medication is prescribed by or in consultation with an endocrinologist, geneticist, or a metabolic disorder specialist.

   b. The requested quantity is within FDA-labeled dosing based on the recipient's weight.

3. Prior Authorization Guidelines:

   a. Initial prior authorization will be for six months.

   b. Recertification approval will be for 12 months.

JJJJ. Tzield® (teplizumab-mzwv)

Therapeutic Class: Disease Modifying Agents for Type 1 Diabetes
Last Reviewed by DUR Board: July 27, 2023

Disease Modifying Agents for Type 1 Diabetes are subject to prior authorization based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board.

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

   a. The recipient is at least eight years of age;

   b. The recipient has a diagnosis of stage 2 type 1 diabetes, confirmed by:

      1. Documenting at least two positive pancreatic islet cell autoantibodies (e.g., glutamic acid decarboxylase 65 [GAD65], insulin autoantibody [IAA), insulinoma-associated antigen 2 autoantibody [IA-2A], zinc transporter 8 autoantibody [ZnT8A], islet cell autoantibody [ICA], and

      2. Documenting dysglycemia without overt hyperglycemia using an oral glucose tolerance test (an alternative method of diagnosis dysglycemia without overt hyperglycemia may be used if an oral glucose tolerance test is not available); and

   c. Prescriber has attested to the absence of acute Epstein-Barr virus (EBV) and cytomegalovirus (CMV) infection through laboratory or clinical evidence; and

   d. Prescriber has confirmed the absence of an active serious infection or chronic active infection, excluding localized skin infection;

   e. The recipient has received all age-appropriate vaccines, with live vaccines administered at least eight weeks before treatment, and inactivated vaccines and mRNA vaccines administered at least two weeks before treatment;

   f. The recipient is not pregnant or planning to become pregnant during the 14-day treatment course; and

   g. It has been prescribed by or in consultation with an adult or pediatric endocrinologist.

2. Quantity Limitations:

   a. 24 vials per 14-day course of therapy.

   b. Maximum one treatment course per lifetime.

   c. Coverage not renewable.

KKKK. Vyjuvek™ (beremagene geperpavec-svdt)

Therapeutic Class: dystrophic epidermolysis bullosa (DEB)
Last reviewed by DUR Board: October 19, 2023

Vyjuvek™ (beremagene geperpavec-svdt) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

   a. The recipient is six months of age or older; and

   b. The recipient has not received a skin graft within the past three months; and

   c. The recipient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) with mutation in the COL7A1 gene; and

   d. Prescribed by or in consultation with pediatric dermatologist or other specialist with advanced knowledge of treating DEB; and

   e. The recipient has cutaneous wound(s) with are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

2. Recertification Request:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reaction resulting in discontinuation of therapy; and

   c. The recipient must have disease response as defined by improvement (healing) of treated wound(s); and

   d. The recipient requires continued treatment for new and/or existing open wounds.

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for six months.

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

LLLL. Hemgenix® (etranacogene dezaparvovec-drlb)

Therapeutic Class: hemophilia B;
Last reviewed by DUR Board: October 19, 2023

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

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

   a. The recipient is at least 18 years of age; and

   b. Prescribed by or in consultation with a hematologist; and

   c. The recipient has a diagnosis of moderately severe or severe congenital factor IX deficiency (e.g., pre-treatment factor IX less than or equal 2%), as confirmed by blood coagulation testing; and

   d. The recipient has one or more of the following:

      1. Currently uses factor IX prophylaxis therapy; or

      2. Current or historical life-threatening hemorrhage; or

      3. Repeated, serious spontaneous bleeding episodes; and

   e. The recipient has been recently tested (within two weeks prior to administration of Hemgenix and found negative for factor IX inhibitors; and

   f. The recipient does not have active hepatitis B and/or hepatitis C infection; and

   g. The recipient does not have uncontrolled HIV infection; and

   h. Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and elastography have been performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and

   i. The recipient has not received previous gene therapy for Hemophilia B; and

   j. Prescriber attestation that factor IX activity will be monitored periodically per package insert (e.g., weekly for three months) post-administration.

2. Recertification Request:

   a. Coverage not renewable.

3. Prior Authorization Guidelines:

   a. Limited to one treatment per lifetime.

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

MMMM. Roctavian™ (valoctocogene roxaparvovec-rvox)

Therapeutic Class: hemophilia A
Last reviewed by DUR Board: October 19, 2023

Roctavian™ (valoctocogene roxaparvovec-rvox) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

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

   a. The recipient is at least 18 years of age; and

   b. Prescribed by or in consultation with a hematologist; and

   c. The recipient has a diagnosis of severe congenital factor VIII deficiency (e.g., pre-treatment factor VIII activity less than 1 IU/dL), as confirmed by blood coagulation testing; and

   d. The recipient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; and

   e. The recipient does not have an active infection, either acute (e.g., acute respiratory infection or acute hepatitis) or uncontrolled chronic (e.g., chronic active hepatitis B); and

   f. The recipient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; and

   g. The recipient has not received prior hemophilia adeno-associated virus (AAV)-vector-based gene therapy; and

   h. The recipient is AAV serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA compliant test; and

   i. The recipient has been tested and found negative for active factor VIII inhibitors (e.g., results from a Bethesda assay or Bethesda assay with Nijmegen modification of under 0.6 Bethesda Units {BU} on two consecutive occasions greater than or equal to one week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba); and

   j. Prescriber attestation that factor VIII activity will be monitored periodically post-administration; and

      1. The recipients with factor VIII activity levels greater than 5 IU/dL should discontinue routine prophylactic exogenous factor VIII; or

2. If factor VIII activity levels decrease and/or if bleeding is not controlled, assess presence of factor VIII inhibitors, and assess the need for hemostatic phrophylaxis.

2. Recertification Request:

a. Coverage not renewable.

3. Prior Authorization Guidelines:

a. Limited to one treatment per lifetime.

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

NNNN. Evkeeza™ (evinacumab-dgnb)

Therapeutic Class: Antihyperlipidemic – Angiopoietin-like protein 3 (ANGPTL3)
Last reviewed by DUR Board: October 19, 2023

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

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

   a. The recipient is at least five years of age; and

   b. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

   c. The recipient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) by any of the following:

      1. Documented DNA test for functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality; or

      2. Untreated LDL-C levels >500mg/dL or treated LDL-C ≥ 300 mg/dL; and

         a. Cutaneous or tendon xanthoma before age 10 year; or

         b. Untreated LDL-C levels in both parents consistent with HeFH; and

   d. The recipient does not have heterozygous familial hypercholesterolemia (HeFH); and

   e. Baseline LDL cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment; and

   f. The recipient has been receiving stable background lipid lowering therapy for ≥ 4 weeks; and

   g. Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PKSK (inhibitors, lomitapide, LDL apheresis; and

   h. The recipient has tried and failed at least a 3-month trial of adherent therapy with ezetimibe used in combination with the highest available or maximally tolerated dose of atorvastatin or rosuvastatin, unless contraindication to statin or ezetimibe; and

   i. The recipient has tried and failed at least a 3-month trial of adherent therapy with combination therapy consisting of the highest available or maximally tolerated dose

of atorvastatin OR rosuvastatin, ezetimibe, and a PCSK9 inhibitor indicated for HoFH (I.E., evolocumab), unless contraindicated; and

j. Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL-C is ≥ 100 mg/dL or ≥ 70 mg/dL for recipients with clinical atherosclerotic cardiovascular disease; and

k. Female recipients must have a negative pregnancy test and have been counselled to use effective contraception during treatment.

2. Recertification Requests

a. Prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology; and

b. The recipient has had a documented reduction in LDL-C when compared to the initial baseline labs; and

c. The recipient continues to adhere to diet and background lipid lowering therapy (e.g., statin, ezetimibe, PCSK9 inhibitor).

3. Prior Authorization Guidelines:

a. Initial approval will be given for three months.

b. Recertification will be approved for six months.

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

OOOO. Joenja® (Leniolisib)

Therapeutic Class:
Last reviewed by DUR Board: October 19, 2023

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

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

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

   b. The recipient weighs at least 45 kg; and

   c. The recipient has a diagnosis of Activated Phosphoinositide 3-kinase Delta Syndrome (APDS) confirmed genetic mutation of either the PIK3CD or PIK3R1 gene; and

   d. Prescribed by or in consultation with immunologist; and

   e. The recipient has nodal and/or extra-nodal lymphoproliferation, with the presence of ≥ 1 measurable nodal lesion as confirmed by prescriber attestation of palpable diagnosis (and/or on computed tomography (CT) or magnetic resonance imaging (MRI); and

   f. The recipient has clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction [e.g., lung, liver]); and

   g. Pregnancy status will be confirmed in female recipients of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment; and

   h. The recipient is not on concurrent immunosuppressive therapy (e.g., mammalian target of rapamycin (mTOR) inhibitors, B-cell depleters, glucocorticoids [doses > 25 mg/day of prednisone equivalent.

2. Recertification request:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells, decrease in disease-related hospitalizations); and

   c. The recipient has not experienced any treatment-restricting adverse effects (e.g.,

severe neutropenia: absolute neutrophil count [ANC] < 500 cells/µL)

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

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

PPPP. Daybue™ (trofinetide)

Therapeutic Class:
Last reviewed by DUR Board: October 19, 2023

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

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

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

   b. The recipient has a diagnosis of typical Rett Syndrome and a documented MECP2 gene mutation confirmed by genetic testing; and

   c. Prescribed by or in consultation with neurologist, geneticist, or developmental pediatrician; and

   d. Prescriber has assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression-Improvement [CGI-I] score, Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale); and

   e. The recipient does not have progressive weight loss prior to initiation of therapy; and

   f. The recipient does not have moderate or severe renal impairment (e.g., eGFR < 45 mL/min/1.73m^2).

2. Recertification request:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced on objective measure or tool (e.g., Rett Syndrome Behavior Questionnaire [RSBQ], CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor scale); and

   c. The recipient has NOT experienced any treatment-restricting adverse effects (e.g., severe diarrhea or dehydration, significant weight loss).

3. Prior Authorization Guidelines:

   a. Initial approval will be given for six months.

   b. Recertification will be approved for 12 months.

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

QQQQ. Elfabrio® (pegunigalsidase alfa-iwxj)

Therapeutic Class:
Last reviewed by DUR Board: October 19, 2023

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

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

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

   b. The recipient has a documented diagnosis of Fabry disease (α -galactosidase A [α-Gal A] deficiency) with biochemical/genetic confirmation by one of the following:

      1. α-Gal-A activity in plasma, isolated leukocytes, and/or cultured cells (males only); or

      2. Detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing; and

   c. Prescribed by or in consultation with a neurologist, geneticist, or other specialist with advanced knowledge in treating Fabry disease; and

   d. The recipient must have a baseline value for plasma GL-3 and/or GL-3 inclusions, plasma or urinary globotriaosylceramide (Gb3/GL-3); or plasma globotriaosylsphingosine (lyso- Gb3); and

   e. Recipient must not be taking migalastat (Galafold) or agalsidase beta (Fabrazyme) during pegunigalsidase alfa-iwxj (Elfabrio) therapy; and

   f. Medication is dosed per FDA labeling of 1 mg/kg (based on actual body weight) administered by IV infusion every two weeks.

2. Recertification requests:

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

   b. Recipient must have experienced a disease response with treatment as defined by a reduction or stabilization in ≥ 1 of the following, as compared to pre-treatment baseline:

      1. plasma GL-3 and/or GL-3 inclusions

      2. plasma or urinary Gb3/GL-3

      3. plasma lyso-Gb3; or

c. The recipient must have experienced a disease response with treatment as defined by an improvement or stabilization in the rate of decline of the estimated glomerular filtration rate (eGFR); and

d. The recipient has not experienced unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, glomerulonephritis).

3. Prior Authorization Guidelines:

a. Initial approval will be given for six months.

b. Recertification will be approved for 12 months.

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

RRRR. Xiaflex® (collagenase clostridium histolyticum)

Therapeutic Class:
Last reviewed by DUR Board: October 19, 2023

Xiaflex® (collagenase clostridium histolyticum) 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. Dupuytren's Contracture:

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

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Dupuytren's Contracture with a palpable cord; and

        3. The recipient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days; and

        4. Documentation that the flexion deformity is causing functional limitations; and

        5. Treatment is administered no sooner than 4-week interval (up to three cycles in total).

    b. Recertification requests:

        1. Recipient continues to meet the above criteria.

    c. Prior Authorization Guidelines:

        1. One treatment cycle.

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

2. Peyronie's Disease

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

        1. The recipient is at least 18 years of age; and

        2. The recipient has a confirmed diagnosis of Peyronie's Disease (PD) with a palpable plaque; and

3. The recipient has curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy and stable disease defined by symptoms (i.e. penile curvature and pain) for at least six months (initial request only); and

4. Xiaflex is NOT being used for sexual or erectile dysfunction associated with Peyronie's Disease; and

5. Must be used in conjunction with penile modeling procedure; and

6. Treatment is administered no sooner than 6-week interval (up to 4 cycles in total).

b. Recertification requests:

1. The recipient continues to meet above criteria; and

2. Curvature deformity remains greater than 15 degrees (curvature <15 degrees does not warrant subsequent treatment cycle).

c. Prior Authorization Guidelines:

1. One treatment cycle.

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

SSSS. Skyclarys® (Omaveloxolone)

Therapeutic Class: Friedreich ataxia
Last reviewed by DUR Board: October 19, 2023

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

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

   a. The Recipient is at least 16 years of age; and

   b. The recipient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; and

   c. The recipient by or in consultation with neurologist, geneticist, or other specialist with advanced knowledge in treating Friedreich's ataxia; and

   d. The recipient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates); and

   e. The recipient has baseline Modified Friedreich's Ataxia Rating Scale (mFARS) score $\geq$ 20 and $\leq$ 80; and

   f. The recipient B-Type Natriuretic Peptide (BNP) is $\leq$ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; and

   g. Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:

      1. Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin; and

      2. Lipid parameter.

   h. The recipient does not have severe hepatic impairment (Child-Pugh C); and

   i. The recipient has the ability to swallow capsules; and

   j. The recipient of reproductive potential have been advised to use non-hormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation.

2. Recertification requests:

   a. The recipient must continue to meet the above criteria; and

   b. The recipient must have disease improvement as defined by stabilization or slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; and

   c. The recipient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction).

3. Prior Authorization Guidelines:

   a. Initial approval will be given for 12 months.

   b. Recertification will be approved for 12 months.

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

4. DIABETIC SUPPLY PROGRAM

Diabetic Supplies 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.

Prior authorization is required for preferred and non-preferred diabetic products (including insulin delivery system and Continuous Glucose Monitor [CGM] receivers and readers).

Preferred diabetic product information is found at:
https://nevadamedicaid.magellanrx.com/cms/nvm/static-assets/documents/NVM_Diabetic_Supplies_Preferred_Product_List.pdf
~~https://www.medicaid.nv.gov/providers/rx/diabeticsupplies.aspx~~

Preferred (including sensors and transmitters) and nonpreferred (including tubing, reservoirs for pumps and transmitters and sensors for CGM's) diabetic supplies do not require a prior authorization. These items require a documented diagnosis of D~~d~~iabetes M~~m~~ellitus T~~t~~ype I (DM1), Diabetes Mellitus Type II (if applicable), or gestational diabetes and recipients must meet all age restrictions stated on the manufacturer's label.

Pharmacy benefit allows a 100-day supply for insulin system and CGM supplies.

A. Preferred Insulin Delivery System

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

a. Recipient must have a documented diagnosis of Diabetes Mellitus Type I or Gestational Diabetes; and

b. The product must be prescribed by or in consultation with an endocrinologist; and

c. The recipient must meet all age restrictions stated in the manufacturer's label; and

d. The recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple day injections of insulin (requiring at least three injections per day); and

e. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL, or

3. Prior use of an insulin pump with documented frequency of glucose self-testing of at least four times per day in the month immediately

prior to the request.

2. Prior Authorization Guidelines

a. Initial prior authorization approval will be for one year.

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

3. Recertification Request

a. Recertification of prior authorization approval will be given if the recipient has documented positive clinical response to the product (including current HbA1C).

b. Recertification prior authorization approval will be for one year.

B. Non-Preferred Insulin Delivery System

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

a. In addition to meeting the "Preferred Insulin Delivery System" criteria, the recipient must also meet the following:

1. The recipient must have been trained to use the non-preferred product; and

2. The recipient must have benefited from use of the non-preferred product; and

3. The recipient must have one of the following reasons/special circumstances:

4. Recipient has had an allergic reaction to a preferred product or related supply; or

5. Recipient has a visual impairment which requires the use of a non-preferred product; or

6. Recipient has medical necessity justification (e.g. mental or physical limitation) which requires them to stay on their current product.

C. Preferred Continuous Glucose Monitors (CGMs)

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

a. Recipient must have a documented diagnosis of Diabetes Mellitus Type I, Diabetes Mellitus Type II, or Gestational Diabetes; and

b. Recipient must meet all age restrictions stated in the manufacturer's label; and

c. Recipient must have been compliant on their current antidiabetic regimen for at least the last six months and this regimen must include multiple daily injections of insulin (requiring at least three injections per day); and

d. One of the following:

1. Documented history of recurring hypoglycemia; or

2. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; or

3. Recipient is currently using insulin pump therapy while continuing to need frequent dosage adjustments or experiencing recurring episodes of severe hypoglycemia (50 mg/dL).

2. Prior Authorization Guidelines

a. Initial prior authorization approval will be for one year.

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

D. Non-Preferred Continuous Glucose Monitor (CGM)

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

a. In addition to meeting the Preferred CGM criteria, the recipient must also meet the following:

1. Recipient has had an allergic reaction to a preferred product or related supply; or

2. Recipient has a visual impairment which requires the use of a non-preferred product; or

3. Recipient has medical necessity justification (e.g. mental or physical limitation) which requires them to stay on their current product; or

4. The recipient must have been trained to use the non-preferred product; and

5. The recipient must have been benefited from use of the non-preferred product.

E. Test Strips and Lancets

Pharmacy Services billing information including Billing Manual and Quantity Limits is available at: https://nevadamedicaid.magellanrx.com/cms/nvm/static-assets/documents/NVM_Diabetic_Supplies_Preferred_Product_List.pdf. ~~https://www.medicaid.nv.gov/providers/rx/billinginfo.aspx~~.

*Blood Glucose monitors with special features (e.g. voice synthesizers) require a prior authorization. For special blood glucose monitors, a diagnosis and a statement from the physician documenting the impairment is required with a prior authorization.