MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

December 14, 2017

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: LYNNE FOSTER, 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.

On August 24, 2017, DUR board approved the inclusion of Exondys 51® (eteplirsen) and Spinraza® (nusinersen) to the drug formulary and will add Siliq® (brodalumab) to the list of Immunomodulators. The Board added, "Previously reviewed by the DUR Board: April 28, 2016" to the section titled "Narcotic Withdrawal Therapy Agents." The board also removed the prior authorization criteria for COX-2 Inhibitors and for Olysio® (simeprevir). The board removed the specific brand names under the therapeutic class of Antimetics.

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 December 18, 2017.

| MATERIAL TRANSMITTED | MATERIAL SUPERSEDED |
|---|---|
| CL 31357<br>Chapter 1200 – PRESCRIBED DRUGS | MTL NONE<br>Chapter 1200 - PRESCRIBED DRUGS |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| **Appendix A. Section B.1-2** | **Cox-2 Inhibitors** | Deleted section. |
| **Appendix A. Section L** | **Immunomodulator Drugs** | Added Siliq® (brodalumab) to the list of drugs. |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| **Appendix A. Section BB** | **Narcotic Withdrawal Therapy Agents** | Added, "Previously reviewed by the DUR Board: April 28, 2017." |
| **Appendix A. Section HH** | **Anti-Hepatitis Agents – Protease Inhibitor Agents** | Removed "and Olysio® (simeprevir)" from the standard disclaimer related to prior authorizations and quantity limitations, (Paragraph 1). Added "and" between brand names Victrelis® (boceprevir) and Inciviek® (telaprevir). Removed comma after Victrelis® (boceprevir). |
| **Appendix A. HH1.a.1.a.** | **Anti-Hepatitis Agents – Protease Inhibitor Agents** | Removed the word "praluent." |
| **Appendix A. Section QQ** | **Antiemetic** | Deleted brand name, "Cesamet® (nabilone) and Marinol® (dronabinol)" from title and body of paragraph.<br><br>Added drug class name, Cannabinoid Antiemetics, to the title and the body of the paragraph. |
| **Appendix A. Section QQ.1.a.** | **Antiemetic** | Deleted brand name, "Cesamet®." Deleted parentheses surrounding "Nabilone." |
| **Appendix A. Section QQ.1.b.** | **Antiemetic** | Deleted brand name, "Marinol®." Deleted parentheses surrounding "Dronabinol." |
| **Appendix A. Section MMM** | **Exondys 51® (eteplirsen)** | Added new drug, Exondys 51® (eteplirsen), and criteria.<br><br>Added Therapeutic Class, Date Reviewed by the DUR Board as August 24, 2017.<br><br>Added standard disclaimer that Exondys 51® (eteplirsen) is subject to prior authorization and quantity limitations.<br><br>Added Coverage and Limitations which must be met and documented.<br><br>Added the recipient must have a diagnosis of Duchenne muscular dystrophy (DMD) and documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping and prescribed by or in consultation with a neurologist who has experience treating children |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| | | and dose will not exceed 30 milligrams per kilogram of body weight once weekly.<br><br>Added Recertification Request Guidelines; authorization for continued use shall be reviewed at least every 12 months when the following criteria are met: One of the following: All of the following: patient has been on therapy for less than 12 months, and patient has experienced clinically significant benefit, and patient is tolerating therapy, and dose will not exceed 30 milligrams per kilogram of body weight once weekly, and prescribed by or in consultation with a neurologist who has experience treating children OR all of the following; patient has been on therapy for 12 months or more and patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients) and patient has experienced clinically significant benefit, and patient is tolerating therapy, and dose will not exceed 30 milligrams per kilogram of body weight once weekly, and prescribed by or in consultation with a neurologist who has experience treating children.<br><br>Added Prior Authorization Guidelines, initial request will be for six months. |
| **Appendix A. Section NNN** | **Spinraza® (nusinersen)** | Added new drug, Spinraza® (nusinersen), and criteria.<br><br>Added Therapeutic Class, Date Reviewed by the DUR Board as August 24, 2017.<br><br>Added standard disclaimer that Spinraza® (nusinersen) is subject to prior authorization and quantity limitations.<br><br>Added Coverage and Limitations which must be met and documented.<br><br>Added the recipient must have a diagnosis of Spinal Muscular Atrophy (SMA) AND prescribed by or in consultation with a neurologist who has experience treating SMA.<br><br>Added Recertification Request Guidelines; authorization for continued use shall be reviewed at least every 12 months when the following criteria are met: One of the following: All of the following: patient has been on therapy for less than 12 months, and patient is |

| Manual Section | Section Title | Background and Explanation of Policy Changes, Clarifications and Updates |
|---|---|---|
| | | maintaining neurological status, and patient is tolerating therapy, and prescribed by or in consultation with a neurologist who has experience in treating SMA.<br><br>Added Prior Authorization Guidelines, initial request will be for 12 months. |

B. Cox-2 Inhibitors

Therapeutic Class: NSAIDs (nonsteriodal anti-inflammatory drugs)
Last Reviewed by the DUR Board: April 28, 2011

Cox-2 Inhibitors are subject to prior authorizations and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer for the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

Indications:

A diagnosis of osteoarthritis, rheumatoid arthritis, alkylosing spondylitis, juvenile rheumatoid arthritis, primary dysmenorrheal or acute pain in adults.

Upon documentation of a listed indication, authorization will be given if the patient meets one of the following criteria:

a. Patient is at high risk of NSAID induced adverse GI events as evidenced by any of the following:

1. Patient has a documented history or presence of peptic ulcer disease.

2. Patient has a history or presence of NSAID-related ulcer.

3. Patient has a history or presence of clinically significant GI bleeding.

b. Patient is greater than 65 years of age.

c. Patient is at risk for GI complications due to the presence of any of the following concomitant drug therapies:

1. Anticoagulants (e.g. warfarin, heparin or Low Molecular Weight (LMW) heparin).

2. Chronic use of oral corticosteroids.

d. Patient has a documented history of inability to tolerate therapy with at least two non-selective (traditional) NSAIDs.

e. The patient is not being treated daily with aspirin for cardioprophylaxis unless concurrent use of a proton pump inhibitor is documented.

f. The patient does not have a documented history of a cardiac event (e.g. stroke, myocardial infarction or has undergone coronary artery bypass graft procedure) in

~~the past six months.~~

~~g. The patient does not have a history of allergies to sulfonamides, aspirin or other NSAIDs.~~

~~2. Prior Authorization Guidelines~~

~~Prior authorization approval may be authorized for up to one year.~~

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

L. Immunomodulator Drugs

Therapeutic Class: Immunomodulators
Last Reviewed by the DUR Board: November 5, 2015

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|---|---|---|
| Actemra® (tocilizumab) | Ilaris ® (canakinumab) | Xeljanz® (tofacitinib) |
| Amevive® (alefacept) | Kineret® (ankinra) | |
| Arcalyst ® (rilonacept) | Orencia® (abatacept) | |
| Cimzia® (certolizumab pegol) | Remicade® (infliximab) | |
| Consentyx® (secukinumab) | Siliq ® (infliximab) | |
| Enbrel® (etanercept) | Simponi® (golimumab) | |
| Entyvio® (vedolizumab) | Simponi® ARIA™ (golimumab) | |
| Humira® (adalimumab) | Stelara® (ustekinumab) | |

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 ≤ six months (early RA) and has high disease activity; and an inadequate or adverse reaction to a disease modifying antirheumatic drug (DMARD) (methotrexate,

BB. Buprenorphine/Naloxone

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: January 26, 2017
Previously reviewed by the DUR Board: April 28, 2016

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

1. Coverage and Limitations

a. To initiate therapy:

1. Buprenorphine/Naloxone will be covered without Prior Authorization (PA) approval for an initial prescription of seven days or less.

a. An ICD diagnosis related to opioid dependence must be written on the prescription and transmitted on the claim.

b. To re-initiate therapy:

1. Buprenorphine/Naloxone will be covered without PA approval to re-initiate therapy for a prescription of seven days or less for recipients with a gap in treatment.

a. An ICD diagnosis related to opioid dependence must be written on the prescription and transmitted on the claim.

c. Prior authorization approval is required to exceed the seven-day limit.

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

Nevada Medicaid encourages recipients to participate in formal substance abuse counseling and treatment.

a. The recipient is 16 years of age or older; and

b. The recipient has a diagnosis of opioid dependence; and

c. Requests for a diagnosis of chronic pain will not be approved; and

d. There is documentation the recipient has honored all of their office visits; and

HH. Anti-Hepatitis Agents – Protease Inhibitor Agents

Therapeutic Class: Anti-Hepatitis Agents-Protease Inhibitors
Last Reviewed by the DUR Board: January 22, 2015

Victrelis® (boceprevir)~~,~~ and Incivek® (telaprevir) ~~and Olysio® (simeprevir)~~ are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

a. Victrelis® (boceprevir)

1. For treatment initiation (treatment weeks five through 28), the recipient ~~praluent~~ must have all of the following:

a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and

b. The recipient will be treated with peginterferon alfa and ribavirin for four weeks prior to starting Victrelis® (boceprevir) and will continue peginterferon alfa and ribavirin for the entire duration of treatment with Victrelis® (boceprevir); and

c. The recipient has not received a previous course of therapy with Incivek® (telaprevir), Olysio® (simeprevir) or Victrelis® (boceprevir) unless the drug is being switched due to an adverse event with the alternative drug.

2. For treatment continuation for treatment weeks 28 through 36, the recipient must have one of the following:

a. The recipient is treatment-naïve and their HCV-RNA level was detectable at treatment week eight and undetectable at treatment week 24; or

b. The recipient is a previous partial responder or a relapser to peginterferon alfa and ribavirin and their HCV-RNA was undetectable at treatment week eight and treatment week 24.

3. For treatment continuation for treatment weeks 28 through 48, the recipient must have one of the following:

QQ. ~~Cesamet® (Nabilone) and Marinol® (Dronabinol)~~Cannabinoid Antiemetics

Therapeutic Class: Antiemetic
Last Reviewed by DUR Board: October 25, 2012

~~Cesamet® (Nabilone) and Marinol® (Dronabinol)~~ Cannabinoid Antiemetics 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 all the following criteria are met and documented:

a. ~~Cesamet® (~~Nabilone~~)~~

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

2. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

b. ~~Marinol® (~~Dronabinol~~)~~

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and

a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and

b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and

c. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or

2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and the

MMM. Exondys 51® (eteplirsen)

Therapeutic Class:Exondys 51® (eteplirsen)
Last Reviewed by the DUR Board: August 24, 2017

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.

1. Coverage and Limitations

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

a. Initial request:

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

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

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

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

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

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

2. The recipient has experienced clinically significant benefit; and

3. The recipient is tolerating therapy; and

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

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

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

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

c. The recipient has experienced clinically significant benefit; and

d. The recipient is tolerating therapy; and

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

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

2. Prior Authorization Guidelines:

a. Prior Authorization approvals will be for:

1. Initial request: six months.

2. Recertification request: one year.

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

NNN. Spinraza® (nusinersen)

Therapeutic Class: Spinraza® (nusinersen)
Last Reviewed by the DUR Board: August 24, 2017

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:

a. Initial request:

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

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

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

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

2. The recipient is maintaining neurological status; and

3. The recipient is tolerating therapy; and

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

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

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

c. The recipient is maintaining neurological status; and

d. The recipient is tolerating therapy; and

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

2. Prior Authorization Guidelines:

a. Prior Authorization approvals will be for:

1. Initial request: twelve months.

2. Recertification request: continued use shall be reviewed at least every 12 months.

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