MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

August 27, 2019

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: TAMMY MOFFITT, CHIEF OF OPERATIONS

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200, Appendix A, are being proposed to reflect recommendations approved on April 25, 2019 by the Drug Use Review (DUR) Board. The proposed changes include revisions to the existing policy on Agents Used for the Treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD), Transdermal Fentanyl, Buprenorphine/Naloxone and Vivitrol® (naltrexone). These proposed changes also include the addition of new prior authorization criteria for Lucemyra™ (lofexidine) and Xyosted™ (testosterone enanthate).

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 September 2, 2019.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32838 MSM Ch 1200 – Prescribed Drugs	MTL N/A MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section C	**Agents Used for the Treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD)**	Removal and re-organization of some of the criteria language. Age of recipient requirement of “six” years has been updated to “five” years.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section F	**Transdermal Fentanyl**	Replacement of the word "encouraged" with the word "required" so that the statement now reads, "Prescribers are required to check the Nevada State Board of Pharmacy's Prescription Monitoring Program (PMP) prior to prescribing narcotic analgesics."
Appendix A Section BB	**Buprenorphine/ Naloxone**	Section title has been revised to read, "Substance Abuse Agents." All existing criteria has been removed and replaced with requiring a diagnosis of opioid dependence on any prescriptions over 24 mg. Addition of new prior authorization criteria for Lucemyra™ (lofexidine). Section ZZ Vivitrol® (naltrexone) has been relocated to this section.
Appendix A Section DD	**Androgel®, Androderm®, Testim® (testosterone gel and transdermal system)**	Section title has been revised to read, "Hormones and Hormone Modifiers." Addition of new prior authorization criteria for Xyosted™ (testosterone enanthate).
Appendix A Section ZZ	**Vivitrol®**	Entire section has been relocated to Section BB, "Buprenorphine/Naloxone."

C. Agents ~~u~~Used for the ~~t~~Treatment of Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD)

Therapeutic Class: ADD/ADHD~~/ADD~~ Agents
Last Reviewed by the DUR Board: ~~January 28, 2016~~April 25, 2019

Agents for the treatment of ~~Attention Deficit Disorder (~~ADD~~)~~/ ~~Attention Deficit Hyperactivity Disorder (~~ADHD~~)~~ are subject to prior authorization and quantity limits 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 ~~for medications~~ will be given if the following criteria is met and documented:

a. General Criteria (Children and Adults)

1. A diagnosis of ADD/ADHD or other FDA approved diagnosis.

~~2.~~ ~~1.~~ Only one long-acting stimulant (amphetamine and methylphenidate products) may be used at a time.~~, a 30-day transitional overlap in therapy will be allowed.~~

3. A 30-day transitional overlap in therapy will be allowed.

~~1. A diagnosis of ADD/ADHD or other FDA approved diagnosis.~~

~~b. ADD/ADHD Criteria (all requests for a diagnosis of ADD/ADHD)~~

~~1. The following criteria must be met and documented in the recipient's medical record prior to treatment with ADD/ADHD agents.~~

~~a. The decision to medicate for ADD or ADHD must be based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: school, home, work or with peers; and~~

~~b.~~4. Other treatable causes of ADD/ADHD have been ruled out.

~~c.~~b. ADD/ADHD Criteria (Children up to age 18 years)

1. The recipient is at least three years of age (shorting-acting stimulants) or at least six years of age (long-acting stimulants, long-acting alpha agonists, atomoxetine).

2. An initial evaluation or regular examination has been done within the past 12 months with the treating prescriber. and medical notes documenting all of the following:

a. A physical evaluation;
b. A developmental history;

c. Any medical and/or psychological history, any history of the primary neurological diagnosis including any history of past psychiatric, psychologic or neurological treatment for ADD/ADHD;

d. Any family history including: psychiatric diagnoses of ADD/ADHD, tic disorder, substance abuse disorder, conduct disorder, anxiety, etc., past or present, family stressors, crises, abuses or neglect and an interview with parent(s) or guardian(s);

e. A review of diagnostic symptoms of ADD/ADHD, presence or absence child behavior checklist, development and context of symptoms and resulting impairment, (school, family, peers), possible alternate or comorbid psychiatric diagnosis;

f. School information, which should include standardized teachers rating scales, achievement tests, neuropsychological testing (if indicated) and speech and language evaluations.

d. Adults (18 years or older)

1. An initial evaluation is documented in the recipient's medical record and must include: a complete psychiatric assessment (present and past), diagnostic symptoms of ADD or ADHD, history of development and context of symptoms and resulting impairment (academic achievement, learning disorder evaluation); and

2. All of the following must be met and documented in the recipient's medical record:

a. A medical history, including medical or primary neurological diagnoses, any history of other psychiatric disorder(s) and the current treatment regimen;

b. A medication review to rule out other possible causes of symptoms (e.g. Phenobarbital, steroids);

c. Diagnostic symptoms of ADD and ADHD;

~~d. An assessment for possible alternate comorbid psychiatric diagnosis (especially: personality disorder, mood disorder, depression or mania, anxiety disorder, dissociatiave disorder, tic disorder including Tourette's disorder and substance abuse disorder); and~~

~~e. Any family history including diagnosis of ADD or ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder, mood disorder and anxiety disorder, possible family stressors, any history of abuse or neglect.~~

2. Exception Criteria

a. Prescriptions for ADD/ADHD medications do not require prior authorization for children five years of age, up to 18 years of age, if the following criteria are met and documented:

1. The recipient is at least ~~six~~ five years of age for short acting stimulants or at least six years of age for long-acting stimulants, long acting alpha agonists, atomoxetine);

2. The medication is prescribed by a psychiatrist; and

3. An ICD code for ADD~~Attention Deficit Disorder~~ with or without ~~H~~hyperactivity is documented on the prescription and transmitted on the claim.

3. Prior Authorization Guidelines

a. Prior authorization approval will be for one year.

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

F. Transdermal Fentanyl

Therapeutic Class: Analgesics, Narcotic
Last Reviewed by the DUR Board: ~~January 22, 2015~~April 25, 2019

Transdermal fentanyl, a narcotic agonist analgesic, is indicated in the management of chronic pain in patients requiring continuous opioid analgesia for pain that cannot be managed by lesser means such as acetaminophen-opioid combinations, non-steroidal analgesics or PRN dosing with short-acting opioids. Transdermal fentanyl 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

Because serious or life-threatening hypoventilation could occur, fentanyl transdermal is contraindicated in management of acute or postoperative pain, mild or intermittent pain responsive to PRN or non-opioid therapy or in doses exceeding 25 mcg/hr at the initiation of opioid therapy. Therefore, patients must meet the following criteria in order to gain prior authorization approval:

a. Patient cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteriodal analgesics or PRN dosing with short-acting opioid.

b. Patient requires continuous opioid administration.

c. Prescribers are ~~encouraged~~ required to check the Nevada State BOPs Prescription Monitoring Program (PMP) prior to prescribing narcotic analgesics. Refer to the PMP website at http://bop.nv.gov/links/PMP/.

d. If transitioning from another opioid, daily morphine equivalent doses are used to calculate the appropriate fentanyl patch dose.

1. Morphine 60-134 mg/day PO; initial Transdermal Fentanyl dose 25 mcg/hr.

2. Morphine 135-224 mg/day PO; initial Transdermal Fentanyl dose 50 mcg/hr.

3. Morphine 225-314 mg/day PO; initial Transdermal Fentanyl dose 75 mcg/hr.

4. Morphine 315-404 mg/day PO; initial Transdermal Fentanyl dose 100 mcg/hr.

5. Morphine 405-494 mg/day PO; initial Transdermal Fentanyl dose 125 mcg/hr.

6. Morphine 495-584 mg/day PO; initial Transdermal Fentanyl dose 150 mcg/hr.

7. Morphine 585-674 mg/day PO; initial Transdermal Fentanyl dose 175 mcg/hr.

8. Morphine 675-764 mg/day PO; initial Transdermal Fentanyl dose 200 mcg/hr.

9. Morphine 765-854 mg/day PO; initial Transdermal Fentanyl dose 225 mcg/hr.

10. Morphine 855-944 mg/day PO; initial Transdermal Fentanyl dose 250 mcg/hr.

11. Morphine 945-1034 mg/day PO; initial Transdermal Fentanyl dose 275 mcg/hr.

12. Morphine 1035-1124 mg/day PO; initial Transdermal Fentanyl dose 300 mcg/hr.

2. Prior Authorization Guidlines

a. Prior authorization approval will be given for ~~a~~ 12 month~~s time period~~.

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

BB. ~~Buprenorphine/Naloxone~~Substance Abuse Agents

Therapeutic Class: Narcotic Withdrawal Therapy Agents
Last Reviewed by the DUR Board: ~~January 26, 2017~~April 25, 2019
~~Previously reviewed by the DUR Board: April 28, 2017~~

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.

Buprenorphine/Naloxone

1. Coverage and Limitations

a. Prior authorization approval will be required for all prescriptions over 24 mg.

b. Requires diagnosis of opioid dependence.

~~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~~

~~e. The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique "X" DEA number; and~~

~~f. All of the following are met:~~

~~1. The recipient will not utilize opioids, including tramadol, concurrently with the requested agent; and~~

~~2. If the recipient is currently utilizing an opioid, medical documentation must be provided stating the recipient will discontinue the opioid prior to initiation of buprenorphine or buprenorphine/naloxone.~~

~~g. Requests for buprenorphine will be approved if one of the following is met:~~

~~1. The recipient is a pregnant female;~~

~~2. There is documentation that the recipient is breastfeeding an infant who is dependent on methadone or morphine;~~

~~3. The recipient has had an allergy to a buprenorphine/naloxone; or~~

~~4. The recipient has moderate to severe hepatic impairment (Child-Pugh B to C).~~

~~d. Requests that exceed the quantity limit must meet all of the following:~~

~~1. There is documentation in the recipient's medical record that the requested dose is the lowest effective dose for the recipient; and~~

~~2. The treatment plan has been provided.~~

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for one year.

   b. Prior Authorization forms are available at:

http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

Lucemyra™ (lofexidine)

1. Coverage and Limitations

   a. A diagnosis of opioid withdrawal with symptoms due to abrupt opioid discontinuation is required; and

   b. The requested quantity does not exceed 2.88 mg/day for up to 14 days.

2. Prior Authorization Guidelines

   a. Prior authorization approval will be for 14 days.

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

~~ZZ.~~ Vivitrol® (naltrexone)

Therapeutic Class: Opioid Dependence Agents
Last Reviewed by the DUR Board: January 28, 2016

Vivitrol® (naltrexone) 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. The drug is being used for an FDA approved indication; and

   b. The drug must be delivered directly to the prescriber's office; and

   c. The drug is only to be administered once per month; and

   d. Routine urine screening and monitoring is recommended.

2. Prior Authorization Guidelines

   a. Prior authorization approvals will be for six months.

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

DD. ~~Androgel®, Androderm®, Testim® (Testosterone gel and transdermal system)~~Hormones and Hormone Modifiers

Therapeutic Class: Androgenic Agents
Last Reviewed by the DUR Board: ~~July 22, 2010~~April 25, 2019

Topical Androgens ~~are subject to prior authorization.~~

1. Coverage and Limitations

   Recipients must meet all of the criteria for coverage:

2. Criteria for approval

   a. Recipient is a male;

   b. Use is for the FDA approved indication:

      Primary (congenital or acquired) or secondary (congenital or acquired) hypogonadism with an ICD code for hypogonadism;

   c. The patient has two morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used;

   d. The patient does not have breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen greater than 4 ng/ml or severe lower urinary symptoms with an International Prostate Symptom Score (IPSS) > 19;

   e. The patient does not have a hematocrit > 50%;

   f. The patient does not have untreated severe obstructive sleep apnea; and

   g. The patient does not have uncontrolled or poorly controlled heart failure.

3. Prior Authorization Guidelines

   a. Prior authorization approval will be for up to one year.

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

   c. ~~Length of authorization: one year.~~

Xyosted™ (testosterone enanthate)

1. Coverage and Limitations with Diagnosis of Hypogonadism

a. Diagnosis of hypogonadism (e.g. testicular hypofunction, male hypogonadism, ICD-10 E29.1); and

b. The recipient is a male patient at birth; and

c. One of the following:

1. Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab; or both of the following:

a. Recipient has a condition that may cause altered sex hormone binding globulin (SHBG) (e.g. thyroid disorder, HIV, liver disorder, diabetes, obesity); and

b. One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab; or

2. Recipient has a history of one of the following: bilateral orchiectomy, panhypopituitarism or a genetic disorder known to cause hypogonadism (e.g. congenital anorchia, Klinefelter's syndrome).

2. Coverage and Limitation with Diagnosis of Gender Dysphoria

a. Diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM); and

b. The recipient is using the hormones to changes their physical characteristics; and

c. The recipient is a female-to-male transsexual.

3. Prior Authorization Guidelines

a. Length of prior authorization approval with diagnosis of hypogonadism will be for one year.

b. Length of prior authorization approval with diagnsosis of gender dysphoria will be for six months for recipients new to testosterone therapy or for 12 months for recipients continuing testosterone therapy without a current authorization on file with OptumRx.

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

~~ZZ. Vivitrol® (naltrexone)~~RESERVED

~~Therapeutic Class: Opioid Dependence Agents~~
~~Last Reviewed by the DUR Board: January 28, 2016~~

~~Vivitrol® (naltrexone) 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. The drug is being used for an FDA approved indication; and~~

~~b.~~a. ~~The drug must be delivered directly to the prescriber's office; and~~

~~c.~~a. ~~The drug is only to be administered once per month; and~~

~~d.~~a. ~~Routine urine screening and monitoring is recommended.~~

~~2. Prior Authorization Guidelines~~

~~a. Prior authorization approvals will be for six months.~~

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