MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

November 26, 2019

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CODY L. PHINNEY, DEPUTY ADMINISTRATOR

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

The Division of Health Care Financing and Policy (DHCFP) proposes revisions to Medicaid Services Manual Chapter (MSM) 1200, Appendix A, to reflect recommendations approved on July 25, 2019 by the Drug Use Review (DUR) Board. The proposed changes include revisions to existing prior authorization criteria for Growth Hormones and Anti-Migraine Medications and new criteria for Spravato™ (esketamine) and Gastrointestinal Agents.

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 2, 2019.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL N/A 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 D	**Growth Hormone**	Brand names have been removed. Patient's age has been updated from third to fifth percentile and new language has been added. Language now reads, "The recipient has a diagnosis of Noonan Syndrome, Prader-Willi Syndrome or Turner Syndrome and their height is as least two standard deviations below the mean or below the fifth percentile for the patient's age and gender and the bone age is less than 16 years for

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		male recipients or less than 14 years for female recipients." Addition of new criteria.
Section S	**Anti-Migraine Medications**	Updated date last reviewed.
Section QQ	**Spravato (esketamine)**	Addition of new prior authorization criteria.
Section WW	**Irritable-Bowel Syndrome Agents**	Title of section has been updated to "Functional Gastrointestinal Disorder Agents." Date last reviewed by has been updated to July 25, 2019. Addition of new prior authorization criteria has been included for Chronic Idiopathic Constipation Agents. Section LLL, titled "Opioid-Induced Constipation Agents" has been relocated to this section for organizational purposes.
Section LLL	**Opioid-Induced Constipation Agents**	Section relocated to Section WW for organizational purposes.

D. Growth Hormones

Therapeutic Class: Growth Hormone
Last Reviewed by the DUR Board: July 25, 2019~~3~~

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

1. Coverage and Limitations

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

~~a. Genotropin® (somatropin); Humatrope® (somatropin); Norditropin® (somatropin); Nutropin® (somatropin); Omnitrope® (somatropin); Saizen® (somatropin); Tev-Tropin® (somatropin):~~

1. Children (up to age 21, with open epiphyses and with remaining growth potential) must meet all of the following:

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

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

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

The recipient must then meet one of the following:

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

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

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

4. The recipient has a diagnosis of chronic renal insufficiency (<75 mL/minute) and bone age is less than 16 years for male or less than 14 years for female; or ~~their height is at least two standard deviations below the mean or below the third percentile for the recipient's age and gender; or~~

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

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

~~6.~~7. The recipient has a diagnosis of growth hormone deficiency or hypothalamic pituitary disease (e.g., hypopituitarism due to structure lesions/trauma to the pituitary including pituitary tumor, pituitary surgical damage, trauma or cranial irradiation), and their height is at least two standard deviations below the mean or below the third percentile for the patient's age and gender and their bone age is less than 16 years for male or less than 14 years for female.

And recipient must meet one of the following:

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

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

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

2. Adults (age 21 years and older, with closed epiphyses and no remaining growth potential) must meet all of the following:

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

S. Anti-Migraine Medications

Therapeutic Class: Serotonin 5-HT1 receptor agonists (triptans)
Last Reviewed by the DUR Board: July 25, 2019 ~~September 21, 2006~~

Therapeutic Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications
Last Reviewed by the DUR Board: October 18, 2018

Serotonin 5-HT1 receptor agonists commonly referred to as "triptans" and CGRP Receptor Inhibitor medications or anti-migraine medications are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

Serotonin 5-HT1 Receptor Agonists (triptans)

1. Coverage and Limitations

An approved prior authorization is required for any prescription exceeding the quantity limits. Approval for additional medication beyond these limits will be considered only under the following circumstances:

a. The recipient's current medication history documents the use of prophylactic medications for migraine headache or the medical provider agrees to initiate such therapy which includes beta-blockers, tricyclic antidepressants, anticonvulsants, Selective Serotonin Reuptake Inhibitors (SSRIs) and/or calcium channel blockers; or

b. The medical provider is aware of and understands the implications of daily use and/or overuse of triptans and agrees to counsel the patient on this issue in an effort to taper the quantity of triptan medication required monthly.

1. Recipient's current medication history must NOT have Monoamine Oxidase (MAO) Inhibitors present for approval of Imitrex® (sumitriptan), Maxalt® (rizatriptan) or Zomig® (zolmitriptan).

2. Recipients whose current medication history indicates the use of propranolol will NOT be granted prior authorization of Maxalt® (rizatriptan) 10mg tablet or 10mg orally disintegrating tablet.

3. Prior authorization will NOT be given to patients with ischemic heart disease.

Approval for exceeding the quantity limits on tripitans will be given for a two month time period.

QQ. ~~RESERVED~~ Spravato™ (esketamine)

Therapeutic Class: Miscellaneous Anti-Depressant
Last Reviewed by the DUR Board: July 25, 2019

Spravato™ (esketamine) is 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

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

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

      2. Recipient must have a diagnosis of treatment resistant depression as evidence of failure of two antidepressants; and

      3. Medication must be administered under the direct supervision of a healthcare provider with post-administration observation; and

      4. Treatment must be in conjunction with an oral antidepressant; and

      5. The medication must be prescribed by or in consultation with a psychiatrist; and

      6. The recipient must not have an aneurism or AV (arteriovenous) malformation.

   b. Approval will not be given for recipients who are currently pregnant or lactating and breastfeeding.

2. Recertification Request:

   a. In addition to the prior authorization criteria listed above (initial approval), the recipient must also have a positive clinical response to the medication treatment.

3. Prior Authorization Guidelines

   a. Initial prior authorization approval will be given for four weeks.

   b. Recertification authorization approval will be given for six months.

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

WW. ~~Irritable Bowel Syndrome Agents~~ Functional Gastrointestinal Disorder Agents

Therapeutic Class: Chronic Idiopathic Constipation (CIC) Agents, Irritable-Bowel Syndrome Agents, Opioid-Induced Constipation Agents
~~Trulance® last reviewed by the DUR Board: July 26, 2018~~
Last Reviewed by the DUR Board: July 25 ~~28~~, 2019 ~~2016~~
~~Viberzi® last reviewed by the DUR Board April 28, 2016~~

~~Irritable Bowel Syndrome~~ Functional Gastrointestinal Disorder Agents 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.

Chronic Idiopathic Constipation (CIC) Agents

1. Coverage and Limitations

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

      1. The requested drug must be FDA approved for the recipient's age; and

      2. Must have a diagnosis of CIC; and

      3. Recipient has trial and failure, contraindication or intolerance to either lactulose or polyethylene glycol (Miralax); and

      4. Recipient has trial and failure, contraindication or intolerance to at least one stimulant laxative, such as sessosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada; and

      5. The maximum allowable dose for CIC indication are as follows:

         a. Linzess® (linaclotide): 145 mcg, once daily

         b. Amitiza® (lubiprostone): 24 mcg, twice daily

         c. Motegrity® (prucalopride): 2mg, once daily

         d. Trulance® (plecanatide): 2mg, once daily

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

Irritable-Bowel Syndrome Agents

1. Coverage and Limitations

   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 requested agent is being prescribed based on FDA approved guidelines; and

         a. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):

            1. For requests for Amitiza® (lubiprostone), the recipient must be female.

            2. The requested dose is appropriate based on indication and age.

               a. Linzess® (linaclotide): 290 µg daily.

               b. Amitiza® (lubiprostone): 16 µg daily.

               c. Trulance® (plecanatide): 3 µg daily.

         b. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):

            1. The medication is being prescribed by or in consultation with a gastroenterologist; and

            2. The requested dose is appropriate based on indication and age.

               a. Lotronex® (alosetron): 0.5 mg twice daily or 1 mg twice daily.

               b. Viberzi® (eluxadoline): 75 mg twice daily or 100 mg twice daily.

               c. Xifaxan® (rifaximin): 550 mg three times a day for 14 days.

2. Prior Authorization Guidelines

a. Prior authorization approval will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

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

Opioid-Induced Constipation Agents

~~Therapeutic Class: Opioid-Induced Constipation Agents~~
~~Last Reviewed by the DUR Board: January 25, 2018~~

~~Opioid-induced constipation agents 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 will be given if all the following criteria are met and documented:

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

b. The requested medication is being used for an FDA approved indication; and

c. The recipient must meet the following criteria:

1. There is documentation in the recipient's medical record of an inadequate response, adverse reaction or contraindication to one agent from three of the four traditional laxative drug classes:

a. Bulk forming laxatives;

b. Osmotic laxatives;

c. Saline laxatives;

d. Stimulant laxatives.

d. And, requests for methylnaltrexone bromide that exceed the quantity limit must meet all of the following criteria:

1. The recipient has opioid-induced constipation in advanced illness, is receiving palliative care and is not enrolled in the DHCFP's hospice program; and

2. The requested dose is 0.15 mg/kg; and

3. The recipient's current weight is >114 kg.

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

LLL. RESERVED ~~Opioid-Induced Constipation Agents~~

~~Therapeutic Class: Opioid-Induced Constipation Agents~~
~~Last Reviewed by the DUR Board: January 25, 2018~~

~~Opioid-induced constipation agents 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.~~

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