## MEDICAID SERVICES MANUAL TRANSMITTAL LETTER

May 23, 2019

TO:CUSTODIANS OF MEDICAID SERVICES MANUALFROM:LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCESUBJECT:MEDICAID SERVICES MANUAL CHANGES<br/>CHAPTER 1200 – PRESCRIBED DRUGS

## **BACKGROUND AND EXPLANATION**

Revisions to Medicaid Services Manual Chapter 1200, Appendix A, are being proposed to reflect recommendations approved on October 18, 2018 by the Drug Use Review (DUR) Board. The recommended changes include the addition of Ilumya® (tildrakizumab), Inflectra® (infliximab), Olumiant® (baricitinib), Otezla® (apremilast), Renflexis® (infliximab) and Taltz® (ixekizumab) to the existing prior authorization criteria for Immunomodulator Medications, the addition of Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor to the existing Anti-Migraine Medications prior authorization criteria and the addition of Opioids Prescribed to Under Age 18 to the existing Opioid PA criteria.

Also proposed are recommendations approved by the DUR Board on January 24, 2019. The recommended changes include the addition of prior authorization criteria for short-acting beta agonists, new criteria for Epidiolex®, revised criteria for compounded medications and new criteria for oral oncology medications and pulmonary arterial hypertension 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 June 3, 2019.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32616 and 32637	MTL N/A
MSM Ch 1200 – Prescribed Drugs	MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section L	Immunomodulator Drugs	Last Reviewed by the DUR Board date updated to October 18, 2018. Addition of Ilumya® (tildrakizumab),

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		Inflectra® (infliximab), Olumiant® (baricitinib), Otezla® ((apremilast), Renflexis® (infliximab) and Taltz® (ixekizumab) to the existing list of immunomodulator drugs.
Appendix A, Section S	Anti-Migraine Medications	Added "Serotonin 5-HT1 receptor agonists (triptans)" to the "Last Reviewed by DUR Board" language for clarity.
		Added "Therapeutic class: Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor" and "Last Reviewed by DUR Board: October 18, 2018."
		Added "Serotonin 5-HT1 receptor agonists (triptans)" title for clarity.
		Added new PA criteria for this therapeutic class.
Appendix A, Section U	Short-Acting Bronchodilators	Renamed section title from "Xopenex® (Levalbuterol) to "Short-Acting Bronchodilators."
		Updated Last Reviewed by the DUR Board date to January 24, 2019.
		Addition of new criteria for short-acting bronchodilators. Removed language under Xopenex® due to repetition.
Appendix A, Section X	Antiemetics- Serotonin Receptor Antagonists	Section QQ titled "Cannabinoid Antiemetics" moved here for organizational purposes.
Appendix A, Section Z	Opioids Opioids Containing	Addition of "Opioids Prescribed to Under Age 18" to title of section and PA criteria.
	Cough Preparations	Added "Opioids Prescribed to Under Age 18" and updated "Last reviewed by DUR Board" to October 18, 2018.
		Added, "Opioids" title for clarity of section.
Appendix A, Section QQ	Cannabinoid Antiemetics	Moved entire section to Section X for organizational purposes.
		Renamed Section title to "Reserved."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section JJJ	Entresto® (sacubitril/ valsartan)	Last Reviewed by the DUR Board date updated to January 24, 2019.
Appendix A, Section XXX 1(a) and (f)	Compounded Medications	Updated Last Reviewed by the DUR Board date to read "January 24, 2019."
<b>I</b> ( <b>u</b> ) <b>u</b> iiu ( <b>i</b> )		Removed language, "Compounded medications at or above \$200 will require a prior authorization."
		Added language, "drugs withdrawn from the market due to safety or effectiveness."
Appendix A, Section ZZZ	Oral Oncology Agents	Addition of new PA criteria for Oral Oncology Agents.
Appendix A, Section AAAA	Pulmonary Hypertension Agents	Addition of new PA criteria for Pulmonary Arterial Hypertension Agents.
Appendix A, Section BBBB	Anticonvulsants	Addition of new section titled "Anticonvulsants" and new PA criteria for Epidiolex® (cannabidiol).

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#### L. <u>Immunomodulator Drugs</u>

Therapeutic Class: Immunomodulators Last Reviewed by the DUR Board: January 25October 18, 2018

Actemra® (tocilizumab)	Ilaris® (canakinumab)	Remicade <sup>®</sup> (infliximab)
Amevive® (alefacept)	Ilumya® (tildrakizumab)	Renflexis® (infliximab)
Arcalyst® (rilonacept)	Inflectra® (infliximab)	Siliq® (brodalumab)
Cimzia® (certolizumab pegol)	Kevzara® (sarilumab)	Simponi <sup>®</sup> (golimumab)
Consentyx <sup>®</sup> (secukinumab)	Kineret <sup>®</sup> (ankinra)	Simponi <sup>®</sup> ARIA <sup>™</sup> (golimumab)
Enbrel® (etanercept)	Olumiant <sup>®</sup> (baricitinib)	Stelara® (ustekinumab)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Taltz® (ixekizumab)
Humira® (adalimumab)	Otezla <sup>®</sup> (apremilast)	Xeljanz <sup>®</sup> (tofacitinib)

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

1. Coverage and Limitations

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

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### S. <u>Anti-Migraine Medications</u>

Therapeutic Class: Serotonin 5-HT1 receptor agonists (<del>T</del>triptans) Last Reviewed by the DUR Board: 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.

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2. Prior Authorization Guidelines

The prior authorization must be initiated by the prescriber. The approved prior authorization must be available if requested.

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

Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitor Medications

- 1. Coverage and Limitations
  - a. Approval will be given if the following criteria are met and documented:

**Episodic Migraines** 

- 1. Initial request:
  - a. The recipient must have a documented diagnosis of episodic migraines; and
  - b. The recipient must be 18 years of age or older; and
  - c. The recipient must have four to 14 migraine days per month, but no more than 14 headache days per month; and

# d. One of the following:

- 1. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or
- 2. The recipient has a contraindication to both Elavil® (amitriptyline) or Effexor® (venlafaxine); and
- e. One of the following:
  - 1. The recipient has documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); or
  - 2. The recipient has a contraindication to both Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); and
- f. One of the following:

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- 1. The recipient has a history of failure (after at least a twomonth trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; or
- 2. The recipient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; and
- g. The medication must not be used in combination with another CGRP Inhibitor.

### Chronic Migraines

- 2. Initial request:
  - a. The recipient has a documented diagnosis of chronic migraines; and
  - b. The recipient must be 18 years of age or older; and
  - c. The recipient has been evaluated for medication overuse headache (MOH) and if the recipient is diagnosed with MOH, then treatment plan will include a taper off the offending medication; and
  - d. The recipient has  $\geq 15$  headache days per month, of which at least eight must be migraine days for at least three months; and

# e. One of the following:

- 1. The recipient has a documented history of failure (after at least a two-month trial) or intolerance to Elavil® (amitriptyline) or Effexor® (venlafaxine); or
  - The recipient has a contraindication to both Elavil® (amitriptyline) or Effexor® (venlafaxine); and
- f. One of the following:

2.

- 1. The recipient has documented history of failure (after at least a two-month trial) or intolerance to Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); or
- 2. The recipient has a contraindication to both Depakote®/Depakote ER (divalproex) or Topamax® (topiramate); and

- g. One of the following:
  - 1. The recipient has a history of failure (after at least a twomonth trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; or
  - 2. The recipient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol or metoprolol; and
- h. The medication will not be used in combination with another CGRP Inhibitor; and
- i. The medication will not be used in combination with Botox (onabotulinumtoxinA).
- 2. Recertification Request:
  - a. The recipient must have documented positive clinical response to CGRP therapy; and
  - b. The use of acute migraine medications (e.g., NSAIDs, triptans) has decreased since the start of CGRP therapy.
- 3. Prior Authorization Guidelines:
  - a. Prior authorization approvals will be for:
    - 1. Initial prior authorization approval: three months.
    - 2. Recertification approval: 12 months.
  - b. Prior Authorization forms are available at: <u>http://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>

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### U. <u>Xopenex® (Levalbuterol)</u>Short-Acting Bronchodilators

Therapeutic Class: Beta Adrenergic Agents Last Reviewed by the DUR Board: July 26, 2012January 24, 2019

Short-Acting Bronchodilators 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. This criteria applies to, but is not limited to, the following list:

Proventil HFA	ProAir HFA	ProAir RespiClick
Ventolin HFA	Albuterol Nebulizer	Nebulizer Solution

a. Coverage and Limitations

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

- 1. Quantity Limits:
  - a. Albuterol Metered Dose Inhalers (MDI): two units per month.
  - b. Albuterol Nebulizer Solution: three bottles of 20ml each or 125 nebulizer units per month.
- 2. In order to exceed the quantity limit, a recipient must meet all of the following:
  - a. The recipient must have a diagnosis of asthma; and
  - b. The recipient has been assessed for causes of asthma and external triggers have been removed or reduced where possible; and
- 3. For recipients 18 years of age or younger the following criteria must be met:
  - a. The recipient has a diagnosis of asthma; and
  - b. The recipient requires an additional inhaler unit for school or equivalent program.
- b. Prior Authorization Guidelines
  - 1. Prior authorization approval will be for 12 months.
  - 2. Prior authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

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- 2. Xopenex® is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.
  - a. <u>1.</u> Coverage and Limitations

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

- 1. Authorization only for recipients experiencing side effects on one other beta-adrenergic agent of any formulation.
- 2. Authorization for patients whose cardiovascular status is considered to be in severe deteriorating condition.
- b. <u>2.</u>—Prior Authorization Guidelines

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

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#### X. Antiemetics <u>Serotonin Receptor Antagonists (also known as 5-HT3 Antiemetics)</u>

Therapeutic Class: Antiemetics, Antivertigo Agents (Serotonin Receptor Antagonists (5 HT3 Antiemetics)

Last Reviewed by the DUR Board: October 28, 2010 Therapeutic Class: Antiemetic (Cannabinoid Antiemetics) Last Reviewed by DUR Board: October 1825, 20182

1. Coverage and Limitations

5-HT3 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.

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:

Serotonin Receptor Antagonists (5 HT3 Antiemetics)

- 1. Coverage and Limitations
  - a. The recipient has failed on chemotherapy-related antiemetic therapy at lower doses; or
  - b. The recipient is receiving chemotherapy treatments more often than once a week; or
  - c. The recipient has a diagnosis of Acquired Immune Deficiency Syndrome (AIDS) associated nausea and vomiting; or
  - d. The recipient has a diagnosis of hyperemesis gravidarum and has failed at least one other antiemetic therapy or all other available therapies are medically contraindicated.
- 2. Prior Authorization Guidelines

A prior authorization to override the quantity limits to allow for a 30-day fill for these drugs may be effective for up to six months.

Cannabinoid Antiemetics

1. Coverage and Limitations

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- a. 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. 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 recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and
  - a. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.
- 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.

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## Z. Opioids, Opioid Containing Cough Preparations, Opioids Prescribed to Under Age 18

Therapeutic Class: Opioids, Last reviewed by the DUR Board: July 26, 2018 Opioid Containing Cough Preparations Last reviewed by the DUR Board: July 26, 2018 Opoids Prescribed to Under Age 18: Last Reviewed by the DUR Board: October 18, 201827, 2016

Opioids, and Opioid Containing Cough Preparations and Opioids Prescribed to Under Age 18 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.

## Opioids

- 1. Coverage and Limitations
  - a. Opioids will be covered without Prior Authorization (PA):
    - 1. For initial prescriptions of seven days or less; and
    - 2. For a total of 13 seven-day prescriptions in any rolling 12 month period; and
    - 3. For prescriptions of 60 mg morphine equivalents or less per day.
  - b. Recipients currently on chronic opioid medications will not be subject to the sevenday requirement for an opioid(s) they have been receiving in the past 45 days.
  - c. Prior Authorization Criteria: To exceed the number of seven-day prescriptions, or to exceed the seven-day limit, or to exceed the 60 mg morphine equivalents or less per day:
    - 1. All of the following criteria must be met and documented:
      - a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and
      - b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.); and
      - c. The lowest effective dose is being requested; and
      - d. A pain contract is on file.
  - d. Exceptions to this policy:

- 1. Recipients with cancer/malignancy related pain; or
- 2. Recipients who are post-surgery with an anticipated prolonged recovery (greater than three months); or
- 3. Recipients receiving palliative care; or
- 4. Recipients residing in a long-term care facility; or
- 5. Recipients receiving treatment for HIV/AIDS; or
- 6. Prescriptions written by or in consultation with a pain specialist.
- 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
- 3. CDC Guidance:
  - a. <u>http://www.cdc.gov/drugoverdose/prescribing/guideline.html</u>.
- 4. Opioid Containing Cough Preparations
  - a. The recipient must be 18 years of age or older.
  - b. Prior authorization approval will be for six months.
  - c. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx.
  - d. For references purposes, codeine and tramadol for children prior authorization criteria can also be found within this chapter in Section TTT.
- 5. Opioids Prescribed to Under Age 18
  - a. Short Acting Opioids will be covered without PA for:
    - 1. Initial prescription of three days or less; and
    - 2. A total of 13 three-day prescriptions in any rolling 12-month period; and
    - 3. Prescriptions of 60 MME or less per day.

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- b. Recipients currently on chronic opioid medications will not be subject to the threeday requirement for an opioid(s) they have been receiving in the past 45 days.
- c. To exceed the number of three-day prescriptions, or to exceed the three-day limit, or to exceed the 60 MME or less per day:
  - 1. All of the following criteria must be met and documented:
    - a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber; and
    - b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, chiropractic treatment, etc.); and
    - c. The lowest effective dose is being prescribed; and
    - d. A pain contract is on file.
- d. Exceptions:
  - 1. Recipients with cancer/malignancy related pain, recipients who are postsurgery with an anticipated prolonged recovery (greater than three months), recipients residing in a long-term care facility, recipients receiving treatment for HIV/AIDS, hospice, palliative care or end-of-life care.
  - 2. Prescriptions written by or in consultation with a pain specialist.
- e. Prior Authorization Guidelines
  - 1. Prior authorization approval will be for three months.
- f. Prescribing Guidance:
  - 1. CDC Guidance: https://www.cdc.gov/drugoverdose/prescribing/guideline.html
  - 2. HHS Opioids and Adolescents: <u>https://www.hhs.gov/ash/oah/adolescent-</u> <u>development/substance-use/drugs/opioids/index.html</u>

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#### QQ. Cannabinoid AntiemeticsRESERVED

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

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. 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. 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 recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and

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

2. Prior Authorization Guidelines

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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.

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JJJ. Entresto® (sacubitril/valsartan)

Therapeutic Class: Angiotension II Receptor Blocker Last Reviewed by the DUR Board: November 5, 2015January 24, 2019

Entresto® (sacubitril/valsartan) is subject to prior authorization 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. The recipient has a diagnosis of chronic heart failure NYHA Class II to IV; and
- b. The recipient has reduced left ventricular ejection fraction (LVEF); and
- c. The recipient is 18 years of age or older; and
- d. The prescriber is a cardiologist or there is documentation in the recipient's medical record that a cardiologist has been consulted; and
- e. The recipient has had a trial of an angiotensin converting enzyme (ACE) or an angiotensin receptor blocker (ARB) for at least four weeks prior to the initiation of therapy; and
- f. The recipient will not concurrently receive an ACE inhibitor; and
- g. The recipient is on an individualized dose of a beta blocker or the recipient has a contraindication to beta blocker use; and
- h. Entresto® will be given twice daily with a maximum dose of 97/103 mg.
- 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

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### XXX. Compounded Medications

Last Reviewed by the DUR Board: July 26, 2018 January 24, 2019

Compounded 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.

1. Coverage and Limitations

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

a. Compounded medications at or above \$200 will require a prior authorization; and

- **b.a**. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and
- e.b. The therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery; and
- d.c. If any prescription ingredients require prior authorization and/or step therapy, all drug specific criteria must also be met; and
- e.d. The compounded medication must not be used for cosmetic purpose; and
- f.e. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (drugs withdrawn from the market due to safety or effectiveness); and
- g.f. The recipient has tried and failed therapy or had an intolerance to at least two FDAapproved, commercially available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:
  - 1. The recipient has a contraindication to commercially available products; or
  - 2. One or no other therapeutic alternatives are commercially available; or
  - 3. Compound medication is prepared in a different dosage form for a recipient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does not meet this criteria); or
  - 4. The recipient has an allergy or sensitivity to inactive ingredients (e.g., dyes,

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#### ZZZ. Oral Oncology Agents

Therapeutic Class: Oral Oncology Agents Last Reviewed by the DUR Board: January 24, 2019

Oral oncology agents are subject to prior authorization 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 (this criteria only applies if other product-specific criteria is not available in MSM Chapter 1200 – Prescribed Drugs)

- a. The recipient has a diagnosis that is indicated in the FDA approved package insert or listed in nationally recognized compendia, for the determination of medically accepted indications; and
- b. If the oral oncology medication is not indicated as a first line agent, either in the FDA approved package insert or nationally recognized compendia, then documentation of previous therapies tried and failed is required; and
- c. The medication is prescribed by or in consultation with an oncologist or hematologist; and
- d. The recipient does not have any contraindications to the requested oral oncology medication; and
- e. The requested quantity and dosing regimen falls within the manufacturer's published dosing guidelines or nationally recognized compendia and is appropriate for the recipient's age; and
- f. The medication must be used in combination with other chemotherapeutic or adjuvant agents according to the FDA approved prescribing information; and
- g. One of the following:
  - 1. If an FDA-approved companion diagnostic test for the requested agent exists, then documentation that the test was performed to confirm the diagnosis is required; or
  - 2. If a test with adequate ability to confirm a disease mutation exists, then documentation that the test was performed to confirm the diagnosis is required.

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- 2. Recertification Request
  - a. Documentation of a positive clinical response to the oral oncology treatment.
- 3. Prior Authorization Guidelines:
  - a. Prior authorization approval will be for 12 months.
  - b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

### MEDICAID SERVICES MANUAL

#### AAAA. Pulmonary Arterial Hypertension Agents

Therapeutic Class: Pulmonary Arterial Hypertension Agents Reviewed by the DUR Board: January 24, 2019

Pulmonary arterial hypertension (PAH) agents are subject to prior authorization 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. The recipient has documented diagnosis of pulmonary arterial hypertension; or
- b. The recipient has one of the following ICD-10 diagnosis codes submitted on the pharmacy claim:

<u>ICD-10</u>	Description
127.20	Pulmonary Hypertension, Unspecified
127.21	Secondary Pulmonary Arterial Hypertension
127.22	Pulmonary Hypertension Due to Left Heart Disease
127.23	Pulmonary Hypertension Due to Lung Diseases and Hypoxia
127.9	Pulmonary Heart Disease, Unspecified

- 2. Prior Authorization Guidelines
  - a. Prior authorization approval will be for one year.
  - b. Prior Authorization forms are available at: <u>http://www.medicaid.nv.gov/providers/rx/rxforms.aspx</u>

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## MEDICAID SERVICES MANUAL

#### BBBB. Anticonvulsants

Therapeutic Class: Anticonvulsants Last Reviewed by the DUR Board: January 24, 2019

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

#### Cannabinoid

Epidiolex® (cannabidiol)

1. Coverage and Limitations

- a. The recipient has a diagnosis of Lennox-Gastaut syndrome or Dravet Syndrome; and
- b. The recipient is two years of age or older; and
- c. A recent serum transaminase (ALT and AST) and total bilirubin level has been obtained and is within normal limits; and
- d. The drug is prescribed by or in consultation with a neurologist; and
- e. The total dose does not exceed 20 mg/kg/day (10mg/kg twice daily); and
- f. The medication will be used as adjunctive therapy (the recipient has been taking one or more antiepileptic drugs and has chart notes confirming the presence of at least four convulsive seizures per month).
- 2. Recertification Request
  - a. Documentation of a positive clinical response to Epidiolex® therapy; and
  - b. Serum transaminase (ALT and AST) and total bilirubin level has been re-checked per package insert.
- 3. Prior Authorization Guidelines
  - a. Initial prior authorization will be for three months.
  - b. Recertification approval will be for 12 months.

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- c. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx
- 4. For anticonvulsant criteria for children and adolescents, refer to Section N, titled Psychotropic Medications for Children and Adolescents.