MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

October 29, 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 update the age in existing prior authorization criteria for Kalydeco® (ivacaftor) from "one year of age and older" to "six months of age and older" and Symdeko® (tezacaftor/ivacaftor) from "12 years of age and older" to "six years of age and older" based on updated Federal Drug Administration (FDA) approved indications.

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 November 4, 2019.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32915 MSM 1200 – Prescribed Drugs	MTL 09/19 MSM 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1(I)(3)	**Immunizations**	Removed, "quadrivalent HPV vaccine, the bivalent HPV vaccine."
Appendix A Section W	**Inhaled Anticholinergic Agents**	Added "Respiratory Anticholinergic Agents" as Therapeutic Class.
Appendix A Section LL 1(A)	**Kalydeco® (ivacaftor)**	Age of recipient requirement of "one year" has been updated to "six months."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section VVV (1)(A)(1)	**Symdeko® (tezacaftor/ivacaftor)**	Age of recipient requirement of "12" years has been updated to "six" years.
Appendix A Section 2(C)	**Gender Edits**	Added the updated diagnosis of "Gender Dysphoria."
Appendix B	**OptumRx Adhoc Reporting System Standard Therapeutic Classes**	Removal of entire section.

1203 POLICY

The Division of Health Care Financing and Policy (DHCFP), Nevada Medicaid, reimburses pharmacies and practitioners for legend (prescription) and non-legend (over the counter) pharmaceuticals dispensed or administered to Medicaid recipients. All prescribers must have a license as a healthcare practitioner, such as a physician, podiatrist, osteopath, dentist, Advanced Practice Registered Nurse (APRN), physician's assistant, etc., keeping within the scope of their practice. The DHCFP requires that pharmaceuticals are written, dispensed and prescribed in accordance with the Nevada State Board of Pharmacy regulations and enforcement.

1203.1 COVERAGE AND LIMITATIONS

A. Covered drugs are subject to prior authorization and/or quantity limits and the following:

1. Section 1927(d)(1)(B)(i) of the Social Security Act (SSA) allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:

   a. American Hospital Formulary Service Drug Information;

   b. United States Pharmacopeia;

   c. DRUGDEX Information System; or

   d. Peer-reviewed medical literature.

2. Pharmaceuticals must be manufactured by companies participating in the Federal Medicaid Drug Rebate Program.

3. Medicaid is mandated by federal statute to require all written (non-electronic) prescriptions for all outpatient drugs for Medicaid recipients to be on tamper-resistant prescription pads. This requirement does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy by telephone by a prescriber. Refer to MSM Addendum for more information on tamper-resistant prescription pads.

4. The Preferred Drug List (PDL) is a list of preferred outpatient drugs established by the Pharmacy and Therapeutics (P&T) Committee. Reference Medicaid Operations Manual (MOM) Chapter 200 for the P&T bylaws. Pharmaceuticals not on the preferred drug list, but within drug classes reviewed by the P&T Committee, require prior authorization, unless exempt under NRS or federal law or excluded through recommendations of the P&T Committee or excluded by the DHCFP.

a. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard Preferred Drug List Exception prior authorization until or if the P&T Committee adds the drug class to the PDL and reviews the product or evidence.

b. New Food and Drug Administration (FDA) approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the list of preferred prescription drugs and are not excluded under state plan or by NRS, are covered with an approved Standard Preferred Drug List Exception prior authorization until the P&T Committee can review the new evidence or drug.

c. Pharmaceuticals may require prior authorization due to step therapy protocols regardless of inclusion in the PDL.

d. If the P&T Committee determines that there are no significant differences between drugs within specific classes based on clinical efficacy and safety, the DHCFP or its Quality Improvement Organization (QIO)-like vendor may consider cost in determining which drugs are selected for inclusion on the PDL.

e. Due to the 76th Special Session and in accordance with Senate Bill (SB) 4, every therapeutic prescription drug that is classified as an anticonvulsant medication or antidiabetic medication that was covered by the Medicaid program on June 30, 2010 must be included on the PDL as a preferred drug. If a therapeutic prescription drug that is included on the list of preferred prescription drugs is prescribed for a clinical indication other than the indication for which it was approved as of June 30, 2010, the Committee shall review the new clinical indication for that drug in accordance with Section 1203 of this chapter.

f. Due to the 76th Special Session and in accordance with SB 4, the P&T Committee must prefer atypical and typical antipsychotic medications that are prescribed for the treatment of a mental illness, anticonvulsant medications and antidiabetic medications for a patient who is receiving services pursuant to Medicaid if the patient:

1. was prescribed the prescription drug on or before June 30, 2010, and takes the prescription drug continuously, as prescribed, on and after that date; and

2. maintains continuous eligibility for Medicaid.

Reference Appendix A for coverage and limitations of medications with special criteria.

B. Standard Preferred Drug List Exception Criteria

Drugs that have a "non-preferred" status are a covered benefit for recipients if they meet the coverage criteria.

1. Coverage and Limitations

a. Allergy to all preferred medications within the same class;

b. Contraindication to or drug-to-drug interaction with all preferred medications within the same class;

c. History of unacceptable/toxic side effects to all preferred medications within the same class;

d. Therapeutic failure of two preferred medications within the same class;

e. If there are not two preferred medications within the same class, therapeutic failure only needs to occur on the one preferred medication;

f. An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or a FDA-approved indication;

g. Psychotropic, Antidepressant Medication – Continuity of Care;

Recipients discharged from an institution on non-preferred psychotropic and/or non-preferred anti-depressant medication(s), their drugs will continue to be covered by Medicaid for up to six months to allow the recipient time to establish outpatient mental health services;

h. For atypical or typical antipsychotic, anticonvulsant and antidiabetic medications, the recipient demonstrated therapeutic failure on one preferred agent.

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

C. Excluded

The DHCFP will not reimburse for the following pharmaceuticals:

1. Agents used for weight loss.

2. Agents used to promote fertility.

3. Agents used for cosmetic purposes or hair growth.

4. Yohimbine.

5. Drug Efficacy Study Implementation (DESI) list "Less than Effective Drugs": In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is identical, related or similar to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the Medicaid Drug Rebate Program. This listing is available on the Centers for Medicare and Medicaid Services (CMS) website at: http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp

   This includes pharmaceuticals designated "ineffective" or "less than effective" (including identical, related or similar drugs) by the FDA as to substance or diagnosis for which prescribed.

6. Pharmaceuticals considered "experimental" as to substance or diagnosis for which prescribed. Pharmaceuticals manufactured by companies not participating in the federal Medicaid Drug Rebate Program unless rated "1-A" by the FDA.

7. Agents used for impotence/erectile dysfunction.

D. Refills

A refill is a prescription subject to the limitations below:

1. Authorized refills are valid only from the pharmaceutical provider dispensing the original prescription, pursuant to Nevada Administrative Code (NAC) Chapter 639.

2. Refill intervals must be consistent with the dosage schedule indicated on the original prescription. If a prescription is for a 34-day supply, a consistent refill would be filled in 30 days; an inconsistent refill date would be filled in 20 days from the original fill. Lost medications: Nevada Medicaid does not pay for replacement of lost, stolen or otherwise destroyed medications even if a physician writes a new prescription for the medication. It is the responsibility of the recipient to replace these medications. Prior authorization may be granted in life-threatening situations and for maintenance medications only. See Maintenance Medications in this section for more information on maintenance medications.

E. Early Refills

1. Nevada Medicaid only pays for up to a 34-day supply of medications (100-day supply for maintenance medications) for recipients each month. A prescription refill will be paid for by Nevada Medicaid only when 80% of the non-controlled substance prescription, and 90% of the controlled substance prescription, is used in accordance with the prescriber's orders on the prescription and on the label of the medication.

2. In the instance that a recipient will be out of town when a refill is due, the pharmacist may enter the appropriate override code to allow an early refill. This override will be monitored by Nevada Medicaid for misuse/abuse by the recipient and/or provider.

3. Medicaid will not pay for an early prescription refill when gross negligence or failure to follow prescriber's prescription instructions has been displayed by the recipient.

F. Maintenance Medications

1. Exceptions to the 34-day supply of medications are allowed for maintenance medications.

2. Maintenance medications are required to be filled in three-month (100-day) supplies.

3. A one-time initial fill of less than three months will be allowed for the first fill to assure tolerability and compliance.

4. Prescription quantities may be reviewed; in those cases where less than a 30-day supply of maintenance drug is dispensed without reasonable medical justification, the dispensing fee may be disallowed.

5. The following drug categories are considered maintenance medications and are required to be filled in three-month (100-day) supplies:

a. Antianginals;

b. Antiarrhythmics;

c. Antidiabetics;

d. Antihypertensives;

e. Cardiac Glycosides;

f. Diuretics;

g. Estrogens; and

h. Progesterone.

6. Contraceptive drugs are considered maintenance medication. Contraceptive drugs that are approved by the FDA are covered up to a 12-month supply.

a. This includes a drug for contraception or its therapeutic equivalent; insertion of a device for contraception; removal of such a device that was inserted while the insured was covered by the same policy of health insurance; education and counseling relating to contraception; management of side effects relating to contraception; and voluntary sterilization for women.

b. Up to three months of contraception may be dispensed immediately, and up to nine months of contraception may be dispensed at the subsequent visit.

c. For a refill following the initial dispensing of a contraceptive drug, the provider may dispense up to a 12-month supply or any amount that covers the remainder rolling year.

d. If a prescription for a contraceptive drug is less than a one-year period, the provider must dispense the contraceptive in accordance with the quantity specified in the prescription order.

7. Anticonvulsants and thyroid preparations are considered maintenance medications, but are not required to be filled in a three-month (100-day) supply.

8. Medications administered in a skilled nursing facility or physician's office are exempt from the three-month (100-day) supply requirement.

9. In long-term care facilities, if the prescriber fails to indicate the duration of therapy for a maintenance drug, the pharmacy must estimate and provide at least a 30-day supply. Exceptions may be based on reasonable stop orders. (For oral liquid medications only, a 16 fluid ounce quantity will be considered sufficient to fulfill the 30-day supply requirement.)

G. Emergency supply of medication

1. In an emergency situation, dispensing of up to a 96-hour supply of covered outpatient drugs that require prior authorization will be allowed.

2. Nevada Medicaid requires prior payment authorization for medications identified as requiring prior authorization.

3. The physician must indicate the diagnosis on the prescription (preferably with an International Classification of Disease (ICD) code) to support the use of the emergency policy.

4. As a follow-up to the dispensing of the emergency supply of medication, the provider must contact the QIO-like vendor to obtain a verbal verification number.

5. An approved PA (if required) will be necessary to get additional medication.

H. Nevada Check Up (NCU)

All coverage and limitation policies and rules, including any prior authorization requirements, outlined in this chapter apply to NCU recipients as well as Nevada Medicaid Fee-for-Service (FFS) recipients. There are NO exceptions.

I. Immunizations

Nevada Medicaid recognizes the importance of preventative health care through vaccines and immunizations. Unless otherwise stated in this chapter, immunizations are covered without prior authorization. Reference Appendix A of this chapter.

1. Childhood Immunizations: All childhood immunizations are covered without prior authorization under the Healthy Kids Program. Refer to MSM Chapter 1500, Healthy Kids Program, for more information on childhood immunizations.

2. Adult Immunizations: Adult immunizations such as tetanus, flu vaccine and pneumococcal vaccine are covered without prior authorization. For a list of covered adult immunizations, please reference the Physician's Fee Schedule under "Professional Rates" at: http://www.dhcfp.nv.gov/RatesUnit.htm

3. Human Papillomavirus (HPV) Vaccine: The ~~quadrivalent HPV vaccine, the bivalent HPV vaccine and the~~ 9-valent HPV vaccine (for both males and females) is covered for Medicaid eligible recipients ages nine years through 45 years, based on the US FDA approved indications. These may be accessed by following the link: http://www.fda.gov/cber/products/gardasil.htm. The HPV vaccines are available through the State Division of Public and Behavioral Health (DPBH) as part of the Vaccines for Children (VFC) program for eligible females and males age nine

W. Inhaled Anticholinergic Agents

Therapeutic Class: Respiratory Anticholinergic Agents
Last Reviewed by the DUR Board:

Inhaled anticholinergic 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. General Criteria

a. Only one inhaled anticholinergic agent may be used in a 30-day period.

LL. Kalydeco® (ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent
Last Reviewed by the DUR Board: July 26, 2018

Kalydeco® (ivacaftor) 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 recipient is ~~one year~~ six months of age or older; and

b. The recipient has a diagnosis of cystic fibrosis; and

c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the gene mutations listed in the FDA-approved package insert; and

d. The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a cystic fibrosis care center.

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

a. Authorization for continued use shall be reviewed at least every 12 months when the following criteria are met:

1. Documentation of a positive clinical response to Kalydeco® therapy.

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.

VVV. Symdeko® (tezacaftor/ivacaftor)

Last Reviewed by the DUR Board: July 26, 2018

Symdeko® (tezacaftor/ivacaftor) 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

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

a. Initial Request:

1. The recipient is ~~12~~ six years of age or older; and

2. The recipient has a documented diagnosis of cystic fibrosis (CF); and

3. The medication must be prescribed by or in consultation with one of the following:

a. Pulmonologist.

b. Specialist affiliated with a CF care center.

4. One of the following:

a. The recipient is homozygous for the F508del mutation as detected by an FDA cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA) approved facility; or

b. The recipient has one of the FDA approved package insert listed mutations on at least one allele in the CF transmembrane conductance regulator (CFTR) gene as detected by FDA cleared cystic fibrosis mutation test or CLIA approved facility.

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

1. Authorization for continued use shall be reviewed at least every 12 months when the following criteria is met:

a. Documentation of a positive clinical response to Symdeko® (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

C. Gender Edits

1. Hormones

a. Estrogen – payable only for female recipients.

b. Progestins – payable only for female recipients.

c. Estrogen and Androgen Combinations – payable only for female recipients.

d. Estrogen and Progestin Combinations – payable only for female recipients.

e. Contraceptive Hormones – payable only for female recipients.

f. Transdermal Testosterone – payable only for male recipients.

g. Androgen Hormone Inhibitor – payable only for male recipients.

2. Exception to the above gender edits:

A diagnosis of Gender Dysphoria (formerly known as Gender Identity Disorder) will bypass the gender edit if the appropriate ICD code is documented on the prescription and transmitted on the claim.

OptumRx AD HOC REPORTING SYSTEM
STANDARD THERAPEUTIC CLASSES

Standard Therapeutic	
Class	Description
00	MEDICAL SUPPLIES
01	ANTI-ULCER PREPS/GASTROINTESTI
02	EMETICS
03	ANTIDIARRHEALS
04	ANTISPASMODIC-ANTICHOLINERGICS
05	BILE THERAPY
06	LAXATIVES
07	ATARACTICS-TRANQUILIZERS
08	MUSCLE RELAXANTS
09	ANTIPARKINSON
10	CNS STIMULANTS
11	PSYCHOSTIMULANTS-ANTIDEPRESSAN
12	AMPHETAMINE PREPARATIONS
13	ALL OTHER ANTIOBESITY PREPS
14	ANTIHISTAMINES
15	BRONCHIAL DILATORS
16	COUGH PREPARATIONS/EXPECTORANT
17	COLD AND COUGH PREPARATIONS
18	ADRENERGICS
19	TOPICAL NASAL AND OTIC PREPARA
20	OPHTHALMIC PREPARATIONS
21	TETRACYCLINES
22	PENICILLINS
23	STREPTOMYCINS
24	SULFONAMIDES
25	ERYTHROMYCINS
26	CEPHALOSPORINS
27	OTHER ANTIBIOTICS
28	URINARY ANTIBACTERIALS
29	CHLORAMPHENICOL
30	ANTINEOPLASTICS
31	ANTIPARASITICS
32	ANTIMALARIALS
33	ANTIVIRALS
34	TB PREPARATIONS
35	TRIMETHOPRIM

~~36~~	~~CONTRACEPTIVES, NON-SYSTEMIC~~
~~37~~	~~VAGINAL CLEANSERS~~
~~38~~	~~GENERAL ANTIBACTERIALS AND ANT~~
~~39~~	~~_____~~

40	NARCOTIC ANALGESICS
41	NON-NARCOTIC ANALGESICS
42	ANTIARTHRITICS
43	ANESTHETICS GEN INHALANT
44	ANESTHETICS GEN INJECT
45	ANESTHETIC LOCAL TOPICAL
46	SEDATIVE BARBITURATE
47	SEDATIVE NON-BARBITURATE
48	ANTICONVULSANTS
49	ANTINAUSEANTS
50	CORTICOTROPINS
51	GLUCOCORTICOIDS
52	MINERALOCORTICOIDS
53	ALDOSTERONE ANTAGONISTS
54	ANTIDOTES
55	THYROID PREPS
56	ANTITHYROID PREPS
57	IODINE THERAPY
58	DIABETIC THERAPY
59	ANABOLICS
60	ANDROGENS
61	ESTROGENS
62	PROGESTERONE
63	SYSTEMIC CONTRACEPTIVES
64	OTHER HORMONES
65	LIPOTROPICS
66	CHOLESTEROL REDUCERS
67	DIGESTANTS
68	PROTEIN LYSATES
69	ENZYMES
70	RAUWOLFIAS
71	OTHER HYPOTENSIVES
72	VASODILATORS CORONARY
73	VASODILATORS PERIPHERAL
74	DIGITALIS PREPARATIONS
75	XANTHINE DERIVATIVES
76	OTHER CARDIOVASCULAR PREPS
77	ANTICOAGULANTS
78	HEMOSTATICS
79	DIURETICS
80	FAT SOLUBLE VITAMINS
81	WATER SOLUBLE VITAMINS
82	MULTIVITAMINS
83	FOLIC ACID PREPARATIONS

~~84~~	~~B COMPLEX WITH VITAMIN C~~
~~85~~	~~VITAMIN K~~
~~86~~	~~INFANT FORMULAS~~
~~87~~	~~ELECTROLYTES & MISCELLANEOUS N~~
~~88~~	~~HEMATINICS & BLOOD CELL STIMUL~~
~~89~~	~~ALLERGENS~~
~~90~~	~~BIOLOGICALS~~
~~91~~	~~ANTIPRURITICS~~
~~92~~	~~COAL TAR~~
~~93~~	~~EMOLLIENTS PROTECTIVES~~
~~94~~	~~FUNGICIDES~~
~~95~~	~~ALL OTHER DERMATOLOGICALS~~
~~96~~	~~HEMORRHOIDAL PREPARATIONS~~
~~97~~	~~OXYTOCICS~~
~~98~~	~~PARASYMPATHETIC AGENTS~~
~~99~~	~~MISCELLANEOUS~~