MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

July 26, 2017

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs were made to reflect approved actions by the Drug Use Review (DUR) Board at the October 26, 2016 and January 26, 2017 meetings.

On October 26, 2016, new prior authorization criteria was approved for Epclusa® (sofosbuvir/ velpatasvir).

On January 26, 2017, revised prior authorization criteria was approved for buprenorphine/ naloxone (Suboxone®/Subutex®), Orkambi® (lumacaftor/ivacaftor) and medications for recipients on hospice. Prior authorization criteria was removed for Incretin Mimetics. Criteria was revised for evaluating recipients for the Lock-in Program.

Renumbering and re-arranging of sections was necessary.

These changes are effective August 1, 2017.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 31133 Prescribed Drugs	MTL 09/17 Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1A(2)(d)	**Eligibility**	Section was divided with new Section 1203.1A(2)(e).
1203.1A(2)(e)	**Lock-in Program**	New section. Verbiage is from Section 1203.1A(2)(d).

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1A(2)(e)(1) (a-d)	**Provider Responsibility**	Under Lock-in Program, added "or" at the end of each sentence in criteria a. through d.
1203.1A(2)(e)(3)	**Provider Responsibility**	Added language, it now reads "Recipients (who are locked in to one pharmacy) or their provider/prescriber can change their lock-in pharmacy at any time by contacting their Medicaid District Office."
Appendix A. (BB)	**Buprenorphine/ Naloxone (Suboxone®/ Subutex®)**	The last reviewed date was revised to January 26, 2017. Added "Previously reviewed by the DUR Board: April 28, 2016".
Appendix A. (BB)(1)(a)	**Buprenorphine/ Naloxone (Suboxone®/ Subutex®)**	New language was added to initiate therapy. Buprenorphine/Naloxone (Subuxone®/Subutex®) will be covered without prior authorization approval for up to seven days if an ICD code related to opioid dependence is written on the prescription and transmitted on the claim.
Appendix A. (BB)(1)(b)	**Buprenorphine/ Naloxone (Suboxone®/ Subutex®)**	New language was added to re-initiate therapy. Buprenorphine/ Naloxone (Subuxone®/Subutex®) will be covered without prior authorization approval to re-initiate therapy for up to seven days if an ICD code related to opioid dependence is written on the prescription.
Appendix A. (BB)(1)(c)	**Buprenorphine/ Naloxone (Suboxone®/ Subutex®)**	Language was added for prior authorization approval to exceed the seven-day limit. Moved the language related to documenting criteria for authorization.
Appendix A. (HH)	**Anti-Hepatitis Agents – Protease Inhibitor Agents**	Removed "and Olysio® (simeprevir)" from the standard disclaimer related to prior authorizations and quantity limitations, (paragraph 1).
Appendix A. (HH)(1)(a)(1)	**Anti-Hepatitis Agents – Protease**	Removed the word "praluent."
Appendix A. (KK)	**Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)**	Revised title to read "Incretin Mimetics."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
	Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)	The last reviewed date was revised to "January 26, 2017." Added "Previously reviewed by the DUR Board: July 26, 2012."
	Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)	Revised the language to the standard disclaimer related to prior authorizations and quantity limitations, (paragraph 1), removing the specific drug names and replacing them with "Incretin Mimetics."
Appendix A. (KK)(1)(a)	**Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)**	New language was added related to documenting an ICD code for diabetes mellitus on the prescription and transmitting it on the claim.
Appendix A. (KK)(1)(b)	**Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)**	New language was added related to a prior authorization documenting an ICD code for diabetes mellitus.
Appendix A. (KK)(1)(a-c)	**Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)**	Removed prior authorization criteria a. through c.
Appendix A. UU(10)	**Hepatitis C direct acting antivirals**	Added prior authorization criteria for Epclusa® (sofosbuvir/velpatasvir). The requested dose is one tab daily for treatment-naïve and treatment-experienced recipients. For the treatment-experienced recipient criteria, documents failed agent and genotype. Treatment duration is 12 weeks.
Appendix A. UU(12)(c)	**Hepatitis C direct acting antivirals**	Under Prior Authorization Guidelines, added "Prior Authorization forms are available at" and the web address.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A. (GGG)	**Medications for Recipients on Hospice**	The last reviewed date was revised to January 27, 2017. Added "Previously reviewed by the DUR Board: January 28, 2016."
Appendix A. (GGG)(1)	**Medications for Recipients on Hospice**	Removed the paragraph under Coverage and Limitations."
Appendix A. (GGG)(1)(a)	**Medications for Recipients on Hospice**	Revised the language for clarity, it now reads "For recipients 21 years of age or older." Deleted the language "The recipient is over the age of 20; and."
Appendix A. (GGG)(1)(a)(3)	**Medications for Recipients on Hospice**	Deleted the language "but is medically necessary to treat the recipient."
Appendix A. (GGG)(1)(a)(4)	**Medications for Recipients on Hospice**	Added new language, "The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient, and."
Appendix A. (GGG)(1)(b)	**Medications for Recipients on Hospice**	New language reads "For recipients 20 years of age or younger."
Appendix A. (GGG)(1)(b)(1-4)	**Medications for Recipients on Hospice**	Added new language related to verification of enrollment in hospice, the medication is not being used to treat or manage symptoms of the terminal diagnosis and palliative care, and medically necessary medications for this age group are covered by the DHCFP.
Appendix A. (HHH)	**Orkambi® (lumacaftor/ ivacaftor)**	The last reviewed date was updated to January 26, 2017. Added "Previously reviewed by the DUR Board: November 5, 2015."
Appendix A. (HHH)(1)(b)	**Orkambi® (lumacaftor/ ivacaftor)**	Updated the recipient age to "6 years of age or older…"

4. If the pharmacist administers the immunization, the dispensing fee will not be reimbursed. An administration fee is paid instead.

10. Pharmacist Submitted Prior Authorizations

a. The DHCFP will allow pharmacists to submit a PA if:

1. The requesting pharmacist has access to the recipient's medical records.

11. Dispensing Practitioners:

a. Must have a current Certificate of Registration through the Nevada State Board of Pharmacy. Refer to NRS 639.070 and NAC 639.390; and

b. Must be enrolled with Nevada Medicaid provider enrollment as a Provider Type 28; and

c. Dispensing practitioners' offices must be located in the State of Nevada; and

d. All prior authorization criteria and quantity limitations apply to dispensing practitioner claims; and

e. Only Provider Type 28 can be reimbursed for a dispensing fee; and

f. All claims must be submitted in the National Council for Prescription Drug Programs (NCPDP) format through Medicaid's Point of Sale (POS) system; and

g. All dispensing practitioners must be compliant with all applicable BOP statutes and regulations.

1203.1A PROVIDER RESPONSIBILITY

1. The pharmaceutical provider will maintain records for all prescriptions dispensed to eligible recipients as may be required.

a. The provider will allow, upon request of proper representative, access to all records that pertain to Medicaid recipients for fiscal review, audit or utilization review.

b. All fiscal records are to be maintained for a period of six years or as specified in federal regulation.

2. Utilization Control

a. Prospective (Concurrent) Drug Utilization Review (Pro-DUR)

Pro-DUR functions will be carried out via the POS Systems.

1. Pro-DUR edits apply to POS claims.

2. Long Term Care (LTC) claims are subject to all Pro-DUR edits that apply to retail.

3. Providers may submit override codes using the (NCPDP) standard interactive DUR codes. Override codes may be submitted on the initial claim. A denied claim does not have to be on file.

4. No long term override codes are issued, codes must be entered each time errors occur. Reference the Nevada Medicaid and NCU Pharmacy Manual (Pharmacy Manual) for more information on the current Pro-DUR edits and override procedures.

5. All drugs are subject to quantity limitations. Refer to the Nevada Medicaid and NCU Pharmacy Manual for established quantity limits.

b. Retro Drug Utilization Review (DUR)

Both recipient and provider profiles (i.e. claim payments) are reviewed to identify patterns of excess. Verification of receipt of services is ongoing on a sample basis. Providers may be audited on site.

c. Drug Utilization Review (DUR)

Nevada Medicaid policy and federal law allows the state appointed DUR Board to conduct review of the information compiled about individual clients and providers and allows the DUR Board to educate Medicaid providers about the changes in drug therapeutics. Educational programs may include information such as drug interactions between medications that physicians have prescribed for the clients and medications they are prescribing that are unnecessarily expensive. In this case, educational efforts will be directed to help providers improve their efficiency in the allocation of the finite resources available for Medicaid clients.

d. Eligibility

Please refer to MSM Chapter 100 for information on Medicaid eligibility, eligibility verification and the Eligibility Verification System (EVS).

e. Lock-in Program~~:~~

When a recipient has shown patterns of abuse/misuse of Nevada Medicaid benefits, or the DHCFP has determined that the recipient requires close medical

management, the recipient may be "locked-in" to a specific pharmacy and/or provider. This means that Medicaid will only pay for controlled substance prescriptions/medical services at a single pharmacy/provider.

1. Criteria that is evaluated by the DHCFP when determining if a recipient should be locked in to a specific pharmacy begins with the number of controlled substance prescriptions filled in 60 days.

   If the recipient has filled ten or more controlled substance prescriptions in the past 60-day period (includes controlled substance pharmaceuticals given in the emergency room) then the clinical review continues with the following criteria:

   a. The recipient has utilized more than one pharmacy in the past 60-day period; or

   b. The recipient has utilized more than three physicians in the past 60-day period; or

   c. The recipient has utilized the emergency room(s) for receiving controlled substances; or

   d. The recipient has been diagnosed with a drug dependency related condition; or

   e. The dispensed quantity per prescription of controlled substances appears excessive by the clinical review team; or the recipient has other noted drug seeking behaviors(s).

2. The POS system will not allow another pharmacy to bill for controlled substance prescriptions, and a message will be given at the time of service to notify the pharmacy that the recipient is locked-in. Any non-controlled substance prescriptions can be filled at any pharmacy.

3. Recipients (who are locked-in to one pharmacy) or their provider/prescriber can change their locked-in pharmacy at any time by contacting their Medicaid District Office.

4. Pharmacies may call the Technical Call Center for an override to the locked-in pharmacy if:

   a. The locked-in pharmacy is out of stock.

   b. The locked-in pharmacy is closed.

BB. Buprenorphine/Naloxone (Suboxone®/Subutex®)

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

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

1. Coverage and Limitations

a. To initiate therapy:

1. Buprenorphine/Naloxone (Suboxone®/Subutex®) 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 (Suboxone®/Subutex®) 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.

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

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. ~~h.~~ 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

KK. ~~Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)~~Incretin Mimetics

Therapeutic Class: Incretin Mimetics
Last Reviewed by the DUR Board: ~~July 26, 2012~~January 26, 2017
Previously reviewed by the DUR Board: July 26, 2012

~~Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)~~Incretin Mimetics 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. An ICD code for Type 2 Diabetes Mellitus is documented on the prescription and transmitted on the claim; or

   b. A prior authorization documenting a diagnosis of Type 2 Diabetes Mellitus has been submitted.

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

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

~~b. The recipient has a diagnosis of type 2 diabetes mellitus; and~~

~~c. The recipient has failed to achieve glycemic control despite an appropriate trial with metformin and/or a sulfonylurea.~~

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

UU. Hepatitis C direct-acting antivirals

Therapeutic Class: Hepatitis C direct acting antivirals
Last Reviewed by the DUR Board: July 28, 2016
Previously reviewed by the DUR Board: January 28, 2016

Hepatitis C direct-acting antivirals 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. Approval will be given if the following criteria are met and documented.

   b. Recipients must meet all of the following criteria:

      1. The recipient has a diagnosis of chronic Hepatitis C Virus (HCV) infection; and

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

      3. All of the following must be included with the PA request:

         a. Medical records and results of laboratory and diagnostic tests which support all of the following:

            1. The HCV genotype (and subtype, if applicable); and

            2. The baseline HCV RNA viral load and date drawn; and

            3. The hepatic fibrosis stage, including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4). (Results of diagnostic tests or imaging studies that are inconclusive may require additional testing); and

         b. A complete treatment regimen; and

         c. The duration of treatment; and

         d. Any previous treatment experience and length of treatment, if any, including outcome (e.g. discontinued due to side effects, relapsed, non-responder, null-responder); and

      4. The prescriber must certify that the treatment will be discontinued if the viral load is detectable at week four of treatment and has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week six (or

thereafter); and

5. Requests for recipients with decompensated cirrhosis (Child Turcotte Pugh (CTP) class B or C) and requests for recipients who have chronic hepatitis C infection status-post liver transplant will be evaluated on a case by case basis.

2. Harvoni® (ledipasvir/sofosbuvir) Initial Requests

a. The requested dose is one 90 mg/400 mg tablet once daily.

b. Genotype 1:

1. The recipient is treatment naïve and must meet one of the following:

a. No cirrhosis, pre-treatment HCV RNA < six million and the requested duration is eight weeks; or

b. No cirrhosis, pre-treatment HCV RNA ≥ six million and the requested duration is 12 weeks; or

c. Compensated Cirrhosis (CTP class A), requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + an NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.

4. The recipient is treatment-experienced (failed Sovaldi + ribavirin ± peginterferon) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 24 weeks.

c. Genotype 4:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), documentation is provided the recipient is unable to take ribavirin and the requested duration is 24 weeks.

d. Genotype 5 and 6:

1. The recipient is treatment-naïve and the requested duration is 12 weeks; or

2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and the requested duration is 12 weeks.

3. Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir) (Initial Requests)

a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg) and one dasabuvir 250 mg tablet twice daily.

b. Genotype 1a:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, recipient will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

c. Genotype 1b:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

4. Technivie® (ombitasvir/paritaprevir/ritonavir) (Initial Requests)

a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg).

b. Genotype 4:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon and ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks.

5. Daklinza® (daclatasvir) (Initial Requests)

a. The requested dose is one of the following:

1. 60 mg (one tablet) daily; or

2. 30 mg (one tablet) and the recipient is receiving a strong CYP3A inhibitor; or

3. 90 mg (one tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer.

b. Genotype 1

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi + ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, documentation has been provided showing the recipient is unable to take ribavirin and

documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

   a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

   b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

   c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

   a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

   b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

   c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing that the recipient is unable to take ribavirin.

c. Genotype 2

1. The recipient is treatment-naïve and must meet one of the following:

   a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

   b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 16 weeks and documentation is provided showing the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing the recipient is unable to take

ribavirin and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 16 to 24 weeks.

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy), documentation has been provided showing the recipient is unable to take peginterferon and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

b. No cirrhosis, will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin.

d. Genotype 3

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing that the recipient is unable to receive peginterferon and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy), documentation is provided that the recipient is unable to receive peginterferon and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.

6. Olysio® (simeprevir) (Initial Request)

a. The requested dose is 150 mg (one capsule) daily.

b. Genotype 1a

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and the recipient is negative for the Q80K polymorphism; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation has been provided showing that the recipient is unable to take ribavirin.

c. Genotype 1b

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

7. <u>Sovaldi® (sofosbuvir) (Initial Requests)</u>

a. The requested dose is 400 mg daily.

b. Genotype 1

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Olysio and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin, the requested duration is 24 weeks and documentation

is provided as to why the recipient cannot use a guideline-recommended regimen; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, documentation is provided showing the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, documentation has been provided that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Olysio and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

c. Genotype 2

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested

duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 16 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation is provided showing the recipient is unable to take ribavirin.

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 16 weeks to 24 weeks, and documentation is provided showing the recipient is unable to take ribavirin; or

e. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to receive peginterferon; or

b. No cirrhosis, will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and documentation has been provided showing that the recipient is unable to receive peginterferon; or

c. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; or

e. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon and ribavirin.

f. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.

d. Genotype 3

1. The recipient is treatment-naive and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

c. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

e. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

f. Compensated cirrhosis (CTP class A) will be treated with Daklinza and ribavirin, the requested duration is 24 weeks; or

g. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with peginterferon and ribavirin and the

requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon; or

c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.

e. Genotype 4

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to

why the recipient cannot use a guideline-recommended regimen; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks, documentation is provided as to why the recipient cannot take peginerferon and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

f. Genotype 5, 6

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

8. Zepatier® (elbasvir and grazoprevir)

a. The requested dose is one tablet (50/100 mg) daily.

b. Genotype 1a

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CTP class A), requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CTP class A), requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

c. Genotype 1b

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and baseline NS5A RAVs for elbasvir have been detected; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

d. Genotype 4

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy; or

c. Compensated cirrhosis (CTP class A), the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy.

9. Recipients who have received previous therapy with an NS5A inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) or combination therapy with sofosbuvir + simeprevir.

a. The recipient must meet one of the following:

1. The recipient has cirrhosis; or

2. Documentation includes the clinical rationale for urgent retreatment.

b. Testing for resistance-associated variants (RAVs) have been done and results have been provided.

c. The requested regimen does not include agents in which RAVs have developed.

d. The requested regimen includes ribavirin or documentation has been provided that ribavirin is contraindicated.

10. Epclusa® (sofosbuvir/velpatasvir)

a. The requested dose is one tab daily; and

1. The recipient is treatment-naïve, with or without cirrhosis and the requested duration is 12 weeks; or

2. The recipient is treatment-experienced, with or without cirrhosis, the requested duration is 12 weeks and must meet one of the following:

a. Genotype 1a, peginterferon + ribavirin treatment experienced; or

b. Genotype 1b, peginterferon + ribavirin treatment experienced; or

c. Genotype 1, HCV nonstructural protein 3 (NS3) protease inhibitor (telaprevir, boceprevir, or simeprivir) plus peginterferon + ribavirin treatment experienced; or

d. Genotype 2, peginterferon + ribavirin treatment experienced; or

e. Genotype 2, sofosbuvir + ribavirin treatment experienced; or

f. Genotype 3, peginterferon + ribavirin treatment experienced; or

g. Genotpe 3, sofosbuvir + ribavirin treatment experienced; or

h. Genotype 4, peginterferon + ribavirin treatment experienced; or

i. Genotype 5 or 6, peginterferon + ribavirin treatment experienced.

~~10.~~11. For requests for recertification (for treatment beyond 12 weeks), the recipient must meet all of the following:

a. Laboratory results for HCV RNA viral load at week four and week six (if applicable) have been submitted with the PA request; and

b. The recipient's HCV viral load must meet one of the following:

1. Undetectable HCV RNA viral load week four; or

2. Detectable HCV RNA viral load at treatment week four and HCV RNA increased by ≤ 10-fold (≤1 $\log_{10}$ IU/mL) on repeat testing at treatment week six (or thereafter).

3. And, the recipient is compliant on all drugs in the treatment regimen.

~~11.~~12. Prior Authorization Guidelines:

a. Prior authorization approval will be for a maximum of 12 weeks (unless the requested regimen is less than 12 weeks long or the remaining duration of therapy is less than 12 weeks).

b. The initial prescription will be limited to a 14-day supply; subsequent refills can be up to 34 days.

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

GGG. Medications for Recipients on Hospice

Last Reviewed by the DUR Board: ~~January 28, 2016~~January 27, 2017
Previously reviewed: January 28, 2016

Medications for recipients on hospice 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

~~Medications for recipients on hospice can be covered by Nevada Medicaid if determined to be not related to the terminal hospice diagnosis. All medications for recipients who are over the age of 20, and enrolled in the hospice program will require prior authorization approval. Approval will be given if all the following criteria are met and documented:~~

a. ~~The~~For recipients 21 years of age or older:~~is over the age of 20; and~~

~~b.~~1. The prescriber has verified the recipient is enrolled in the hospice program; and

~~c.~~2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

~~d.~~3. The requested medication is not being used for palliative care ~~but is medically necessary to treat the recipient~~; and

4. The requested medication is unrelated to the terminal hospice diagnosis and is medically necessary to treat the recipient; and

~~e.~~5. The requested medication is not providing a curative or long-term prophylactic therapy.

b. For recipients 20 years of age or younger:

1. The prescriber has verified the recipient is enrolled in a hospice program; and

2. The requested medication is not being used to treat or manage symptoms of the terminal hospice diagnosis; and

3. The requested medication is not being used for palliative care.

4. Medically necessary curative medications for this age group are covered by the DHCFP pursuant to Sections 1905(o)(1) and 2110(a)(23) of the SSA.

2. Prior Authorization Guidelines

   a. Prior Authorization approval will be for three months.

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

HHH. Orkambi® (lumacaftor/ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent
Last Reviewed by the DUR Board: ~~November 5, 2015~~January 26, 2017
Previously reviewed November 5, 2015

Orkambi® (lumacaftor/ivacaftor) 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

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

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

   b. The recipient is ~~12~~ 6 years of age or older; and

   c. The recipient is homozygous for the F508del mutation in the CFTR gene; and

   d. The requested dose is two tablets every 12 hours; or

   e. The requested dose is one tablet every 12 hours in the presence of severe hepatic impairment.

2. Prior Authorization Guidelines:

   a. Prior Authorization approvals will be for one year.

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