MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

January 29, 2019

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 Chapter 1200, Appendix A, are being proposed to reflect recommendations approved on July 26, 2018 by the Drug Use Review (DUR) Board. The proposed changes include the addition of Eucrisa® to the existing prior authorization (PA) criteria for Topical Immunomodulators, the addition of new PA criteria for opioid cough preparations, new PA criteria for antihemophilia agents, revisions to the existing Hepatitis C (Anti-Hepatitis Agents and Hepatitis C direct acting antivirals) criteria, amendments to the existing PA for Kalydeco®, the addition of Trulance® to the existing Irritable-Bowel Syndrome Agents, the addition of new PA criteria for Symdeko®, existing Botulinum Toxin PA was relocated and revised from Chapter 600 to Chapter 1200, and the addition of new PA for compounded medications.

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 February 4, 2019.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 32274 MSM Ch 1200 – Prescribed Drugs	MTL N/A MSM Ch 1200 – Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section M, (1)(b)(2) and (1)(e)	**Topical Immunomodulators**	Addition of prior authorization (PA) criteria for Eucrisa® to existing criteria for Topical Immunomodulators.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A, Section Z	**Opioids**	Drug title updated to read, "Opioids, Opioid Containing Cough Preparations." Addition of opioid cough preparations PA criteria to the existing Opioids criteria.
Appendix A, Section GG	**Reserved**	Title now reads "Antihemophilia Agents." Addition of new PA criteria.
Appendix A, Section HH	**Anti-Hepatitis Agents – Protease Inhibitor Agents**	Title of section has been changed to now read, "Anti-Hepatitis Agents." Removal of all PA criteria for Victrelis® and Incivek® (these drugs no longer exist). Language from Section UU was utilized to re-organize and re-write all Anti-Hepatitis Agents by drug name.
Appendix A, Section LL. (1)(c) and (d)	**Kalydeco® (ivacaftor)**	Amendments made to existing PA criteria which include: adding language so that (1)(c) reads, "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." The listed gene mutations were removed. The following language was added to (1)(d), "The medication is prescribed by or in consultation with a pulmonologist or a specialist affiliated with a cystic fibrosis care center" and recertification request language was added (2).
Appendix A, Section UU	**Hepatitis C direct acting antivirals**	Title of section changed to "Reserved." Removal of entire section. All language was utilized to re-organize and re-write all Anti-Hepatitis Agents criteria by drug name, which has been re-located to Section HH.
Appendix A, Section WW (1)(a), (2)(a), (2)(c)	**Irritable-Bowel Syndrome Agents**	Drug names were updated for consistency throughout and Trulance® criteria was added.
Appendix A, Section VVV	**Symdeko® (tezacaftor/ ivacaftor)**	Addition of new PA criteria.
Appendix A, Section WWW	**Botulinum Toxin**	Addition of new PA criteria.
Appendix A, Section XXX	**Compounded Medications**	Addition of new PA criteria.

M. Topical Immunomodulators

Therapeutic Class: ~~Immunomdulators,~~ Topical Immunomdulators
Eucrisa® last reviewed by the DUR Board: July 26, 2018
Last Reviewed by the DUR Board: April 26, 2007

~~Elidel®~~
~~Protopic®~~

Topical Immunomodulators drugs are a subject to prior authorization and quantity limitations 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

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

   a. Patient must have a therapeutic failure with the use of a topical steroid.

   b. Patient has a documented diagnosis of Atopic Dermatitis:

      1. Elidel®~~:~~ for mild to moderate, for ages ≥ two years.

      2. Eucrisa® for mild to moderate, for ages ≥ two years.

      ~~2.~~3. Protopic® 0.03%; moderate to severe, for ages ≥ two years.

      ~~3.~~4. Protopic® 0.1%; moderate to severe, for ages ≥ 18 years.

   c. Not for chronic use.

   d. Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.

   e. The recipient must have had therapeutic failure with the trial of a topical steroid of at least 14 days within the last six months for approval of Eucrisa®.

   ~~e.~~f. Not recommended for use in immunocompromised patients.

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

Z. Opioids, Opioid Containing Cough Preparations

Therapeutic Class: Opioids, Last reviewed by DUR Board: July 26, 2018
Opioid Containing Cough Preparations Last reviewed by DUR Board: July 26, 2018
Last Reviewed by the DUR Board: October 27, 2016

Opioids and Opioid Containing Cough Preparations 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. 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 seven-day 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. http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

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.

GG. ~~Reserved~~Antihemophilia Agents

Therapeutic Class: Antihemophilia Agents
Last Reviewed by DUR Board: July 26, 2018

Antihemophilia 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. Coverage and Limitations

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

a. The medication being prescribed must be for an FDA approved indication; or

b. One of the following:

1. The diagnosis is supported as a use of American Hospital Formulary Service Drug Information (AHFS DI); or

2. The diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table); or

3. Both of the following:

a. Diagnosis is listed in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of III or Class Indeterminant (see DRUGDEX Strength of Recommendation table); and

b. Efficacy is rated as “effective” or “evidence favors efficacy” (see DRUGDEX Efficacy Rating and Prior Authorization Approval Status table); or

4. Diagnosis is supported in any other section of DRUGDEX; or

5. The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal; and

a. One of the following:

1. The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice; or

2. The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

   a. AHFS Compendium;

   b. Thomson Reuters (Healthcare) Micromedex/ DRUGDEX (not Drug Points) Compendium;

   c. Elsevier Gold Standard's Clinical Pharmacology Compendium;

   d. National Comprehensive Cancer Network Drugs and Biologics Compendium; and

6. The dispensing provider will monitor the amount of product a recipient has left to avoid over-stock; and

7. The prescriber is a specialist in treating hemophilia; and

8. A new prior authorization will be required for any dose adjustment in excess of 5% (increase or decrease).

2. 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

HH. Anti-Hepatitis Agents ~~– Protease Inhibitor Agents~~

Therapeutic Class: Anti-Hepatitis Agents ~~Protease Inhibitors~~
Last Reviewed by the DUR Board: ~~January 22, 2015~~July 26, 2018

~~Victrelis® (boceprevir) and Incivek® (telaprevir)~~Anti-Hepatitis Agents are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the SSA Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

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

~~a. Victrelis® (boceprevir)~~

~~1. For treatment initiation (treatment weeks five through 28), the recipient must have all of the following:~~

~~a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and~~

~~b. The recipient will be treated with peginterferon alfa and ribavirin for four weeks prior to starting Victrelis® (boceprevir) and will continue peginterferon alfa and ribavirin for the entire duration of treatment with Victrelis® (boceprevir); and~~

~~c. The recipient has not received a previous course of therapy with Incivek® (telaprevir), Olysio® (simeprevir) or Victrelis® (boceprevir) unless the drug is being switched due to an adverse event with the alternative drug.~~

~~2. For treatment continuation for treatment weeks 28 through 36, the recipient must have one of the following:~~

~~a. The recipient is treatment naïve and their HCV-RNA level was detectable at treatment week eight and undetectable at treatment week 24; or~~

~~b. The recipient is a previous partial responder or a relapser to peginterferon alfa and ribavirin and their HCV-RNA was undetectable at treatment week eight and treatment week 24.~~

~~3. For treatment continuation for treatment weeks 28 through 48, the recipient must have one of the following:~~

a. ~~The recipient has a diagnosis of chronic hepatitis C genotype 1 with compensated cirrhosis and their HCV-RNA was detectable at treatment week 24; or~~

b. ~~The recipient had a <2 $\log_{10}$ HCV-RNA drop by treatment week 12 on prior treatment with peginterferon alfa and ribavirin and HCV-RNA on triple therapy is undetectable at treatment week 24; or~~

c. ~~The recipient is treatment naïve and poorly interferon responsive based on <1 $\log_{10}$ decline in HCV-RNA at treatment week four following lead-in therapy with peginterferon alfa.~~

~~b. Incivek® (telaprevir)~~

~~1. For treatment initiation (weeks one through eight) the recipient must have all of the following:~~

~~a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and~~

~~b. The recipient will be treated with concomitant peginterferon alfa plus ribavirin; and~~

~~c. The recipient has not received a previous course of therapy with Incivek® (teaprevir), Olysio® (simeprevir) or Victrelis® (boceprevir) unless the drug is being switched due to an adverse event with the alternative drug.~~

~~2. For treatment continuation for treatment weeks nine through 12:~~

~~a. The recipient is treatment naïve and their HCV-RNA level was <1000 IU/mL at treatment week four.~~

2. ~~Prior Authorization Guidelines:~~

~~a. Victrelis® (boceprevir)~~

1. ~~Initial prior authorization will be for 24 weeks (through treatment week 28).~~

~~2. For recipients meeting criteria for continuation treatment for treatment weeks 28 through 36, a prior authorization may be renewed once for an additional eight weeks.~~

~~3. For recipients meeting criteria for continuation treatment for treatment weeks 28 through 44, a prior authorization may be renewed once for an additional 24 weeks.~~

~~b. Incivek® (teleprevir)~~

~~1. Initial prior authorization approval will be for eight weeks.~~

~~2. For recipients meeting criteria for continuation treatment for treatment weeks nine through 12, a prior authorization approval may be renewed once for an additional four weeks.~~

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

a. Daklinza® (daclatasvir) for genotype 1 or 3

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The medication is used in combination with Sovaldi® (sofosbuvir); and

3. One of the following:

a. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or

b. Both of the following:

1. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and

2. The medication is used in combination with Ribavirin; and

4. The recipient has not failed a prior HCV NS5A-containing regimen (e.g., Daklinza); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

6. Prior authorization approval will be for 12 weeks.

b. Epclusa® (sofosbuvir and velpatasvir)

1. The following are required for all Epclusa® treatment:

a. The recipient is not receiving Epclusa® (sofosbuvir and velpatasvir) in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1, 2, 3, 4, 5 or 6, without decompensated liver disease

c. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

d. The recipient must not have decompensated liver disease; and

e. Epclusa® must be used alone; and

f. Prior authorization approval will be for 12 weeks.

3. Genotype 1, 2, 3, 4, 5 or 6 with decompensated liver disease

a. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has decompensated liver disease; and

c. Epclusa® is being used in combination with Ribavirin; and

d. Prior authorization approval will be for 24 weeks.

4. Genotype 1, 2, 3, 4, 5 or 6 Ribavirin intolerance/ineligible or prior Sovaldi® (sofosbuvir) or NS5A-based treatment failure.

a. The recipient has a documented diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has decompensated liver disease; and

1. One of the following:

a. The recipient is Ribavirin intolerant or ineligible; or

b. Both of the following:

1. The recipient has had prior failure (defined as viral relapse, breakthrough while on therapy, or is a non-responder to therapy) to Sovaldi® or NS5A-based treatment; and

2. Eplcusa® is used in combination with Ribavirin; and

c. Prior authorization approval will be for 24 weeks.

c. Harvoni® (ledipasvir/sofosbuvir)

1. The following are required for all Harvoni® treatment:

a. The recipient is not receiving Harvoni® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi®, Olysio®); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is less than six million IU/mL

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient does not have cirrhosis; and

c. The recipient is treatment naïve; and

d. Medical records documenting pre-treatment HCV RNA less than six million IU/mL must be submitted; and

e. Prior authorization approval will be for eight weeks.

3. Genotype 1, treatment naïve, without cirrhosis and pre-treatment HCV RNA is greater than or equal to six million IU/mL

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient does not have cirrhosis; and

c. The recipient is treatment naïve; and

d. Medical records documenting pre-treatment HCV RNA greater than or equal to six million IU/mL must be submitted; and

e. Prior authorization approval will be for 12 weeks.

4. Genotype 1, treatment naïve with compensated cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

c. The recipient is treatment naïve; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

e. Prior authorization approval will be for 12 weeks.

5. Genotype 1, treatment experienced without cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient does not have cirrhosis; and

c. One of the following:

1. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; or both of the following:

a. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) except in combination with Olysio® (simeprevir); and

b. The medication is used in combination with Ribavirin.

d. Prior authorization approval will be for 12 weeks.

6. Genotype 1, Ribavirin eligible, treatment experienced and with compensated cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

c. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

d. The medication is used in combination with Ribavirin; and

e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

f. Prior authorization approval will be for 12 weeks.

7. Genotype 1, Ribavirin ineligible, treatment experienced and with compensated cirrhosis

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

   b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

   c. The recipient has experienced treatment failure with a previous treatment regimen that included peginterferon plus Ribavirin or an HCV protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) plus peginterferon plus Ribavirin; and

   d. The recipient is Ribavirin ineligible; and

   e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

   f. Prior authorization approval will be for 24 weeks.

8. Genotype 1, 4, 5 or 6, decompensated cirrhosis or post-liver transplant

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

   b. One of the following:

      1. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); or

      2. Both of the following:

         a. The recipient is a liver transplant recipient; and

         b. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

   c. The medication is used in combination with Ribavirin; and

   d. Prior authorization approval will be for 12 weeks.

9. Genotype 1,4, 5, or 6, decompensated cirrhosis, Ribavirin ineligible or prior failure of Sovaldi® or NS5A based regimen

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

   b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has decompensated cirrhosis (e.g., Child-Pugh class B or C); and

   c. One of the following:

      1. The recipient is Ribavirin ineligible; or

      2. Both of the following:

         a. The recipient has experienced treatment failure with a previous treatment regimen that included Sovaldi® (sofosbuvir) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

         b. The medication is used in combination with Ribavirin; and

   d. Prior authorization approval will be for 24 weeks

10. Genotype 4, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

   b. One of the following:

      1. The recipient is treatment naïve; or

      2. One of the following:

         a. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and is without cirrhosis; or

         b. Both of the following:

1. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin and has compensated cirrhosis (Child-Pugh class A); and

2. The medication is used in combination with Ribavirin; and

c. Prior authorization approval will be for 12 weeks.

11. Genotype 5 or 6, treatment naïve or treatment experienced (peginterferon plus Ribavirin)

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. One of the following:

1. The recipient is treatment naïve; or

2. The recipient has experienced failure with a previous treatment regimen that included peginterferon plus Ribavirin; and

c. Prior authorization approval will be for 12 weeks.

d. Mavyret® (glecaprevir/pibrentasvir)

1. The following are required for all Mavyret® treatment:

a. The recipient is not receiving Mavyret® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir)); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of

HIV Medicine)

2. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve without cirrhosis

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

   b. The recipient is treatment naïve; and

   c. The recipient is without cirrhosis; and

   d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

   e. Prior authorization approval will be for eight weeks.

3. Genotype 1, 2, 3, 4, 5 or 6, treatment naïve with compensated cirrhosis

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

   b. The recipient is treatment naïve; and

   c. The recipient has compensated cirrhosis (Child-Pugh class A); and

   d. Prior authorization approval will be for 12 weeks.

4. Genotype 1, treatment experienced (prior failure to an NS3/4A protease inhibitor), without decompensated cirrhosis

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

   b. The recipient has experienced failure with a previous treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

   c. The recipient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

e. Prior authorization approval will be for 12 weeks.

5. Genotype 1, treatment experienced (prior failure to an NS5A inhibitor), without decompensated cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

c. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)); and

d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

e. Prior authorization approval will be for 16 weeks.

6. Genotype 3, treatment experienced (interferon or Sovaldi® based regimen), without decompensated cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

c. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

d. The recipient is without decompensated cirrhosis (Child-Pugh class B or C); and

e. Prior authorization approval will be for 16 weeks.

7. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), without cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

c. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

d. The recipient is without cirrhosis; and

e. Prior authorization approval will be for eight weeks.

8. Genotype 1, 2, 4, 5 or 6, treatment experienced (interferon or Sovaldi® based regimen), with compensated cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has experienced failure with a previous treatment regimen that included interferon, peginterferon, Ribavirin, and/or Sovaldi® (sofosbuvir); and

c. The recipient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (e.g., Daklinza® (daclatasvir)); and

d. The recipient has compensated cirrhosis (e.g., Child-Pugh class A); and

e. Prior authorization approval will be for 12 weeks.

e. Olysio® (simeprevir)

1. Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

   a. Both of the following:

      1. Diagnosis of chronic hepatitis C genotype 1a; and

      2. The recipient does not have the NS3 Q8K polymorphism; or

   b. The recipient has a diagnosis of chronic hepatitis C genotype 1b; or

   c. The recipient has a diagnosis of chronic hepatitis C genotype 4; and

2. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

3. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

4. The medication is used in combination with peginterferon alfa and Ribavirin; and

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

   a. Hepatologist

   b. Gastroenterologist

   c. Infectious Disease Specialist

   d. HIV Specialist (certified through the American Academy of HIV Medicine)

6. Genotype 1 without cirrhosis

   a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

   b. The recipient is without cirrhosis; and

   c. The medication is used in combination with Sovaldi® (sofosbuvir).

d. Prior Authorization Guidelines

e. Prior authorization approval will be for 12 weeks.

7. Genotype 1 with cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of medical records (e.g., chart notes, laboratory values documenting that the recipient has cirrhosis; and

c. The medication is used in combination with Sovaldi® (sofosbuvir); and

d. Prior authorization approval will be for 24 weeks.

f. Sovaldi® (sofosbuvir)

1. The following is required for all Sovaldi® treatment:

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1 or 4, without decompensated liver disease

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 or 4 (submission of medical records e.g., chart notes, laboratory values); and

b. The medication is used in combination with peginterferon alfa and Ribavirin; and

c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

d. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

e. Prior authorization approval will be for 12 weeks.

3. Genotype 3, without decompensated liver disease

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient must be 18 years of age or older; or

c. Both of the following:

1. The recipient has a documented diagnosis of chronic hepatitis C virus (HCV) genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is 12 to 17 years of age; or both of the following:

a. The recipient weighs at least 35 kg; and

b. The recipient is less than 12 years of age; and

d. The medication is used in combination with Ribavirin; and

e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

f. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

g. Prior authorization approval will be for 24 weeks.

4. Genotype 2, without decompensated liver disease

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient must be 18 years of age or older; or

c. Both of the following:

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 2 (submission of medical records e.g., chart notes, laboratory values); and

2. The recipient is 12 to 17 years of age; or both of the following:

a. The recipient weighs at least 35 kg; and

b. The recipient is less than 12 years of age; and

d. The medication is used in combination with Ribavirin; and

e. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

f. The recipient has not experienced failure with a previous treatment regimen that includes Sovaldi®; and

g. Prior authorization approval will be for 12 weeks.

5. Genotype 1, without cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The medication is used in combination with Olysio® (simeprevir); and

c. The recipient is without cirrhosis; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

e. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

f. Prior authorization approval will be for 12 weeks.

6. Genotype 1, with cirrhosis

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The medication is used in combination with Olysio® (simeprevir); and

c. The recipient has cirrhosis; and

d. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

e. The recipient has not experienced failure with a previous treatment regimen that includes Olysio® or other HCV NS3/4A protease inhibitors (e.g., Incivek® (telaprevir), Victrelis® (boceprevir)); and

f. Prior authorization approval will be for 12 weeks.

7. Genotype 1

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The medication is used in combination with Daklinza® (daclatasvir); and

c. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

d. One of the following:

1. The recipient is without decompensated cirrhosis and is not a liver transplant recipient; or

2. Both of the following:

a. The recipient has decompensated cirrhosis and/or is a liver transplant recipient; and

b. The medication is used in combination with Ribavirin.

e. Prior authorization approval will be for 12 weeks.

8. Genotype 3

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes,

laboratory values); and

b. The medication is used in combination with Daklinza® (daclatasvir); and

c. The recipient has not experienced failure with a previous HCV NS5A treatment regimen (e.g., Daklinza® (daclatasvir)); and

d. One of the following:

1. The recipient is without cirrhosis and is not a liver transplant recipient; or

2. Both of the following:

a. The recipient has cirrhosis (compensated or decompensated) and/or is a liver transplant recipient; and

b. The medication is used in combination with Ribavirin.

e. Prior authorization approval will be for 12 weeks.

g. Technivie® (ombitasvir, paritaprevir and ritonavir) for genotype 4

1. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

2. One of the following:

a. The recipient is without cirrhosis; or

b. The recipient has compensated cirrhosis; and

3. The medication is used in combination with Ribavirin; and

4. The recipient is not receiving Technivie® in combination with another HCV direct acting agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

5. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and

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

a. Hepatologist

b. Gastroenterologist

c. Infectious Disease Specialist

d. HIV Specialist (certified through the American Academy of HIV Medicine)

7. Prior authorization approval will be for 12 weeks.

h. Viekira Pak, Viekira XR® (ombitasvir, paritaprevir, ritonavir tablets, dasabuvir tablets)

1. The following is required for all Viekira Pak, Viekira XR® treatment:

a. The recipient has not experienced failure with a previous treatment regimen that includes HCV NS3/4A protease inhibitor (e.g., Incivek® (telaprevir), Olysio® (simeprevir), Victrelis® (boceprevir)) or an NS5A inhibitor (Daklinza® (daclatasvir)); and

b. The recipient is not receiving Viekira® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1a or mixed genotype 1, without cirrhosis and without liver transplant

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is without cirrhosis; and

c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 12 weeks.

3. Genotype 1a or mixed genotype 1, with cirrhosis and without liver transplant

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the recipient has cirrhosis; and

c. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 24 weeks.

4. Genotype 1b, without liver transplant

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

c. Prior authorization approval will be for 24 weeks.

5. Genotype 1 (regardless of sub genotype), with liver transplant

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1 (submission of medical records e.g., chart notes, laboratory values); and

b. Submission of documentation that the recipient is a liver transplant recipient; and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g.,

METAVIR fibrosis score less than or equal to F2); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 24 weeks.

i. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

1. The following is required for all Vosevi® treatment:

a. The recipient is without decompensated liver disease (e.g., Child-Pugh class B or C); and

b. The recipient is not receiving Vosevi® in combination with another HCV direct acting antiviral agent (e.g., Harvoni® (ledipasvir), Zepatier® (elbasvir/grazoprevir)); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1, 2, 3, 4, 5 or 6; without decompensated cirrhosis, prior relapse to NS5A based regimen

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is a previous relapser to an NS5A based regimen (e.g., Daklinza® (daclatasvir), Epclusa® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Technivie® (ombitasvir/ paritaprevir/ ritonavir), Viekira® (ombitasvir/ paritaprevir/ ritonavir/dasabuvir), Zepatier® (elbasvir/grazoprevir); and

c. Submission of medical records (e.g., chart notes or laboratory values) documenting normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2); and

d. Prior authorization approval will be for 12 weeks.

3. Genotype 1a, without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

c. Prior authorization approval will be for 12 weeks.

4. Genotype 3, without decompensated cirrhosis, prior relapse to sofosbuvir based regimen without an NS5A inhibitor

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 3 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is a previous relapser to a sofosbuvir based regimen without an NS5A inhibitor; and

c. Prior authorization approval will be for 12 weeks.

j. Zepatier® (elbasvir/grazoprevir)

1. The following is required for all Zepatier® treatment:

a. The recipient does not have moderate to severe hepatic impairment (e.g., Child-Pugh class B or C); and

b. The recipient is not receiving Zepatier® in combination with another HCV direct acting antiviral agent (e.g., Sovaldi® (sofosbuvir), Olysio® (simeprevir)); and

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

1. Hepatologist

2. Gastroenterologist

3. Infectious Disease Specialist

4. HIV Specialist (certified through the American Academy of HIV Medicine)

2. Genotype 1a, treatment naïve, or PegIFN/RBV experienced or PegIFN/RBV/protease inhibitor experienced, without NS5A polymorphisms

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1a (submission of medical records e.g., chart notes, laboratory values); and

b. One of the following:

1. The recipient is treatment naïve; or

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

3. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir); and

c. Both of the following:

1. The recipient has been tested for the presence of NS5A resistance associated polymorphisms; and

2. The recipient has baseline NS5A resistance associated polymorphisms (e.g., polymorphisms at amino acid positions 28, 30, 31, or 93); and

d. The medication is used in combination with Ribavirin; and

e. Prior authorization approval will be for 16 weeks.

3. Genotype 1b, treatment naïve, or PegIFN/RBV experienced or PegIFN/RBV/protease inhibitor experienced

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 1b (submission of medical records e.g., chart notes, laboratory values); and

b. One of the following:

1. The recipient is treatment naïve; or

2. The recipient has had prior failure to peginterferon alfa plus Ribavirin treatment; or

3. Both of the following:

a. The recipient has had prior failure to treatment with peginterferon alfa plus Ribavirin plus an HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir); and

b. The medication is used in combination with Ribavirin; and

c. Prior authorization approval will be for 12 weeks.

4. Genotype 4, treatment naïve

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient is treatment naïve; and

c. Prior authorization approval will be for 12 weeks.

5. Genotype 4, PegIFN/RBV experienced

a. The recipient has a documented diagnosis of chronic hepatitis C genotype 4 (submission of medical records e.g., chart notes, laboratory values); and

b. The recipient has had prior failure to peginterferon alfa plus Ribavirin; and

c. The medication is used in combination with Ribavirin; and

d. Prior authorization approval will be for 16 weeks.

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

LL. Kalydeco® (ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent
Last Reviewed by the DUR Board: ~~September 3, 2015~~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 two years 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 ~~following~~ gene mutations listed in the FDA-approved package insert; and~~: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.~~

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.

UU. ~~Hepatitis C direct-acting antivirals~~RESERVED

~~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. Sovaldi® (sofosbuvir) (Initial Requests)

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.

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.

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

WW. Irritable-Bowel Syndrome Agents

Therapeutic Class: Irritable-Bowel Syndrome Agents
Trulance® last reviewed by DUR Board: July 26, 2018
Last Reviewed by the DUR Board: July 28, 2016
Viberzi® last reviewed by the DUR Board April 28, 2016

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

1. Coverage and Limitations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Prior Authorization Guidelines

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

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

VVV. Symdeko® (tezacaftor/ivacaftor)

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

2. Prior Authorization Guidelines:

   a. Prior authorization approval will be given for 12 months.

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

WWW. Botulinum Toxin

Therapeutic Class: Neurotoxic Protein
Last reviewed by DUR Board: July 26, 2018

Botulinum toxins 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. Policy

Botulinum toxin injections are a Nevada Medicaid covered benefit for certain spastic conditions including, but not limited to cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis. The injections may reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and ambulation, to allow improved range of motion, to permit better physical therapy and provide adequate perineal hygiene.

2. Coverage and Limitations

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

a. It is expected that physicians be familiar with and experienced in the use of botulinum toxin products and utilize FDA-approved product labeling, compendia and peer-reviewed scientific literature to select the appropriate drug and dose regimen for each recipient condition. A complete list of covered indications can be found within the "Provider Type 20, 24, and 77 Billing Guide" applicable to botulinum toxins.

b. Documentation must be provided that the recipient has been unresponsive to conventional methods of treatment (e.g., medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions); and

c. If maximum dose is reached and positive clinical response is not established, treatment must be discontinued; and

d. Documentation of medical necessity is required for treatment more frequent than every 90 days; and

e. Coverage will be approved for one injection per site. A site is defined as including muscles of a single contiguous body part, such as a single limb, eyelid, face or neck.

f. Coverage will not be provided for injections given for cosmetic or for investigational purposes.

3. 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 Botulinum Toxin therapy.

4. Prior Authorization Guidelines

a. Prior authorization approval will be for six months.

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

XXX. Compounded Medications

Last Reviewed by DUR Board: July 26, 2018

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. Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated; and

c. 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. If any prescription ingredients require prior authorization and/or step therapy, all drug specific criteria must also be met; and

e. The compounded medication must not be used for cosmetic purpose; and

f. The compounded medication must not include any ingredient that has been withdrawn or removed from the market due to safety reasons; and

g. The recipient has tried and failed therapy or had an intolerance to at least two FDA-approved, 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, preservatives, sugars, etc.) that are found in commercially available

products.

2. Prior Authorization Guidelines

a. Prior authorization approval will be for six months unless the provider requests for a shorter length of therapy.

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