**Drug Utilization Review (DUR) Committee**

November 20th 2015

**Members Present**

Jenny Love, MD
John Pappenheim, MD
Chuck Semling, PharmD
Erin Narus, PharmD (DHSS)
Rebecca Wall, PharmD (DHSS)

**Members Absent**

Robin Cooke, PharmD, CGP
Maggi Rader, CNM
Trish White

**Non-Members Present**

Tina Hawkins, PharmD (Magellan)
Ryan Ruggles, PharmD (New Member)

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Meeting started at approximately 1:05 pm; Attendance was taken

(1) Review of minutes from April 17th meeting
    Minutes will be discussed and approved via email.
(2) Review of agenda
    Approved unanimously without modification
(3) Comments/Suggestions from Committee members
    a. A member of the committee mentioned difficulty, as well a longer than usual hold time, while trying to get a prior authorization for quetiapine quantity limits. The call center staff has been re-educated regarding proper procedures and a root cause analysis is being completed. More details will be discussed at the January meeting.
(4) Prospective Drug Utilization Review (ProDUR) / Clinical Topic Areas:
    a. New Prescription Medications
        i. Orkambi
            1. Dr. Wall gave a brief overview of Orkambi, including its indication and drug interactions.
            2. Alaska is expecting to treat 4 patients with Orkambi. F508del homozygous is expected to be in about 47% of all CF patients, or about 30,000 patients in the US. Estimated 8,600 patients in the US would be eligible for Orkambi.
            3. Proposed Criteria:
                a. CRITERIA FOR APPROVAL:
                    i. Diagnosis of Cystic Fibrosis; AND
                    ii. The patient is greater than or equal to 12 years old; **AND**
                    iii. The patient is homozygous for the F508del mutation in the CFTR (cystic fibrosis transmembrane regulator) gene from a FDA-cleared CF mutation test; OR
                    iv. If lab results from the patient's CF mutation test are not available, provide documentation relating to how the prescriber knows that the patient has the F580del mutation; AND
                    v. If being co-administered with a strong CYP3A inducer (i.e. rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort, etc.) with dosage adjustment or discontinuation of the inducer; AND

vi. If being co-administered with a sensitive CYP3A substrate, or a CYP3A substrate with a narrow therapeutic index (i.e. midazolam, triazolam, cyclosporine, everolimus, sirolimus, and tacrolimus, etc.) with dosage adjustment or discontinuation of either interacting medication.

b. CRITERIA CAUSING DENIAL:
   i. Patient does not have a confirmed diagnosis of Cystic Fibrosis; OR
   ii. The patient is less than 12 years old; OR
   iii. The patient has an unknown F580del mutation status, or is not homozygous for the F508del mutation; OR
   iv. Orkambi is being co-administered with a strong CYP3A inducer, or a sensitive CYP3A substrate, or a CYP3A substrate with a narrow therapeutic index, without adjusting therapy to compensate for the drug/drug interaction.
c. LENGTH OF AUTHORIZATION:
   i. Initial coverage may be approved for 2 months.
   ii. Re-authorization, may be approved for up to 10 months if documentation of clinical improvement is submitted
d. DISPENSING LIMIT: The dispensing limit is a 30 day supply of the medication.
e. QUANTITY LIMIT: Maximum 4 doses per day; up to a 30 day supply (120 tablets).

4. It was suggested that a confirmatory chloride sweat test be added to the criteria.
5. Committee Motion:
   a. CRITERIA FOR APPROVAL:
      i. Diagnosis of Cystic Fibrosis, accompanied with results from a positive sweat test; AND
      ii. The patient is greater than or equal to 12 years old; **AND**
      iii. The patient is homozygous for the F508del mutation in the CFTR (cystic fibrosis transmembrane regulator) gene from a FDA-cleared CF mutation test; OR
      iv. If lab results from the patient's CF mutation test are not available, provide documentation relating to how the prescriber knows that the patient has the F580del mutation; AND
      v. If being co-administered with a strong CYP3A inducer (i.e. rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort, etc.) with dosage adjustment or discontinuation of the inducer; AND
      vi. If being co-administered with a sensitive CYP3A substrate, or a CYP3A substrate with a narrow therapeutic index (i.e. midazolam, triazolam, cyclosporine, everolimus, sirolimus, and tacrolimus,

etc.) with dosage adjustment or discontinuation of either interacting medication.

b. CRITERIA CAUSING DENIAL:
    i. Patient does not have a confirmed diagnosis of Cystic Fibrosis; OR
    ii. The patient is less than 12 years old; OR
    iii. The patient has an unknown F580del mutation status, or is not homozygous for the F508del mutation; OR
    iv. Orkambi is being co-administered with a strong CYP3A inducer, or a sensitive CYP3A substrate, or a CYP3A substrate with a narrow therapeutic index, without adjusting therapy to compensate for the drug/drug interaction.
c. LENGTH OF AUTHORIZATION:
    i. Initial coverage may be approved for 2 months.
    ii. Re-authorization, may be approved for up to 10 months if documentation of clinical improvement is submitted
d. DISPENSING LIMIT: The dispensing limit is a 30 day supply of the medication.
e. QUANTITY LIMIT: Maximum 4 doses per day; up to a 30 day supply (120 tablets).

Pending approval and consult with pulmonology specialist.
Passed Unanimously

b. Review of existing Prior Authorizations, Quantity Limits, Edits
    i. FDA Indication Changes
    ii. FDA Label Changes
    iii. Periodic Review
        1. Hepatitis C, Directing Acting Agents
            a. Dr. Wall discussed changes in the class since the last review by the Committee, including new medications, new warnings and new FDA-approved indications.
            b. The following criteria recommendations were discussed:

**Criteria for Approval: Treatment Naïve:**

1. Adult patient age ≥ 18 years old; **AND**
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype 2, 3, or 4 (GT 2, 3, or 4), and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. Agrees to complete regimen; **AND**
5. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); or any positive results are to be explained by prescriber; **OR**
    a. If the urine confirmation test is positive, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse; **AND**
6. If HCV/HIV co-infected, prescriber must provide documentation of CD4 count, HIV viral load, and regimen.

**Criteria for Renewal Authorization Approval, with Approval Duration:**

1. For regimens with durations longer than 12 weeks, HCV RNA must be submitted for treatment weeks 4 and 8; **AND**
2. HCV RNA < 25 IU/mL at treatment week 4; **OR**
3. If HCV RNA detectable at treatment week 4, HCV RNA at week 6 is lower than week 4 or undetectable.
4. The prescriber must maintain documentation in the patient's medical chart of the following information: HCV RNA level at treatment weeks 4 and 8, as well as HCV RNA levels after completion of therapy at week 12 post therapy (SVR12), and week 24 post therapy (SVR24). This information shall be made available upon request.
5. Based on HCV genotype and prior treatment experience
   - Refer to Table 1 for regimen durations; authorization duration will be approved as follows:

| Regimen Duration | Authorization Duration |
|---|---|
| 12 weeks | 12 weeks |
| 24 weeks | 12 weeks + 12 weeks* |

   *or under the discretion of Alaska Medicaid
6. Lost or stolen medication replacement requests will not be authorized.

**Regimen: Treatment Naïve:**

**Table 1†**

| Genotype | Regimen | Duration | |
|---|---|---|---|
| | | | **Exclusions** |
| GT 2<br>*Metavir F2-4* | sofosbuvir + ribavirin‡,§ | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | | | **Exclusions** |
| GT 3<br>*Metavir F2-4* | sofosbuvir + ribavirin‡,§ | 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 3<br>*Metavir F2-4* | daclatasvir + sofosbuvir | 12 weeks | *Concomitant use with strong CYP3A inducer, severe renal impairment, ESRD* |
| | | | |
| GT 4<br>*Metavir F2-4, Child-Pugh A, treatment naïve* | Technivie + ribavirin‡,§ | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C), pregnancy* |
| GT 4<br>*Metavir F2-4* | sofosbuvir + ribavirin‡,§ | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4* | sofosbuvir + ledipasvir | 12 weeks | |
| GT 4<br>*Metavir F2-4, Child-Pugh A, treatment naïve, cannot take* | Technivie‡ | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C)* |

| Table 1[†] | | | |
|---|---|---|---|
| **Genotype** | **Regimen** | **Duration** | |
| *or tolerate ribavirin* | | | |
| | | | |
| GT 5 or 6<br>*Metavir F2-4* | sofosbuvir + ledipasvir | 12 weeks | |
| | | | |
| GT 2,3,4<br>*Hepatocellular carcinoma awaiting liver transplantation AND Meets Milan criteria: In single hepatocellular (HC) carcinomas, tumor ≤ 5 cm in diameter, OR In multiple HC carcinomas, no more than 3 tumor nodules, each ≤ 3 cm in diameter, AND No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.* | sofosbuvir + ribavirin[‡,§] | 48 weeks *or until liver transplant* | *Severe renal impairment, ESRD; pregnancy* |
| **Restricted to Specialist** | | | |
| GT 2, 3, 4, 5, 6<br>*decompensated cirrhosis* | | | *Restricted to Specialist* |
| Mixed genotype | | | *Restricted to Specialist* |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration; [‡]Weight based ribavirin; [§]Refer to FDA approved labeling for use in individuals with impaired renal function

**Sovaldi, Technivie, and Daklinza Criteria for Denial:**

1. Patient is not abstaining from the use of illicit drugs and alcohol as evidenced by submitted urine confirmation test results, without documentation submitted that the patient is actively attending a treatment program for substance abuse.
2. Diagnostic/disease severity evidence is not submitted with the request.
3. HCV RNA results not submitted with the request.
4. For regimens containing ribavirin, patient is pregnant or lactating.
5. HCV genotype is 1a or 1b (refer to respective criteria).

| Table 2: Additional Criteria for Denial[†] | | | | |
|---|---|---|---|---|
| Sovaldi | Severe renal | Child-Pugh score greater | Taking a | Genotype 5 or 6 |

| | | | | |
|---|---|---|---|---|
| | impairment (eGFR < 30 mL/ min/ 1.73m$^2$) or end stage renal disease (ESRD) requiring hemodialysis | than 6 [class B or C] and treatment is not being managed by a liver disease specialist | concomitant drug that has a significant clinical interaction or is contraindicated | infection |
| Technivie | Moderate to severe hepatic impairment: Child-Pugh score greater than 6 [class B or C] | Taking a concomitant drug that has a significant clinical interaction or is contraindicated with any of the agents (e.g., highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious events, or drugs that are moderate or strong inducers of CYP3A) | Co-infection with HIV-1, without a current suppressive antiretroviral drug regimen | Genotype 1, 2, 3, 5 or 6 infection |
| Daklinza | Concomitant use with a drug that strongly induces CYP3A | Presence of a NS5A Y93H polymorphism | Genotype 1, 2, 4, 5 or 6 infection | |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration

**Criteria for Approval: Treatment Experienced Patients:**

1. Adult patient age ≥ 18 years old; **AND**
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype 2, 3, or 4 (GT 2, 3, or 4), and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. Agrees to complete regimen; **AND**
5. For patients previously treated with an NS5A inhibitor, NS5B inhibitor or a NS3/4a protease inhibitor, polymorphism testing results MUST be submitted; **AND**
6. If HCV/HIV co-infected, must provide documentation of CD4 count, HIV viral load, and regimen; **AND**.
7. Documentation of previously trialed HCV therapies, dates of therapy, whether full therapy was completed or discontinued early, and, if discontinued early, the reason for the discontinuation is included in the authorization request; **AND**
8. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); or any positive results are to be explained by prescriber; **OR**
    a. If the urine confirmation test is positive, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.

**Regimen: Treatment Experienced:**

| Table 3[†] | | | | |
|---|---|---|---|---|
| **Genotype** | **Failed Treatment** | **Regimen** | **Duration** | |
| | | | | **Exclusions** |
| GT 2<br>*Metavir F2-4* | Peg-interferon + ribavirin | Sofosbuvir + ribavirin | 16 weeks OR 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | | | | **Exclusions** |
| GT 3<br>*Metavir F2-4* | Sofosbuvir alone or with ribavirin +/- peg-interferon | Sofosbuvir + daclatasvir + ribavirin[‡,§] | 12 weeks | *Severe renal impairment, ESRD; pregnancy, Concomitant use with strong CYP3A inducer* |
| | | | | **Exclusions** |
| GT 4<br>*Metavir F2-4* | Sofosbuvir +/- ribavirin +/- peg-interferon | sofosbuvir + ledipasvir+ ribavirin[‡,§] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4, Child-Pugh A* | Sofosbuvir +/- ribavirin +/- peg-interferon | paritaprevir + ombitasvir + ritonavir + ribavirin[‡,§] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C), pregnancy* |
| GT 4<br>*Metavir F2-4* | Simeprevir + ribavirin, + peg-interferon<br>OR<br>Sofosbuvir + simeprevir<br>OR<br>Ritonavir + paritaprevir + ombitasvir | sofosbuvir + ledipasvir+ ribavirin[‡,§] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4, Child-Pugh A* | Peg-interferon + ribavirin | paritaprevir + ombitasvir + ritonavir + ribavirin[‡,§] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C), pregnancy* |
| GT 4<br>*Metavir F2-4* | Peg-interferon + ribavirin | sofosbuvir + ribavirin[‡,§] | 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4* | Peg-interferon + ribavirin | sofosbuvir + ledipasvir | 12 weeks | |
| | | | | |
| GT 5 or 6<br>*Metavir F2-4* | | sofosbuvir + ledipasvir + ribavirin[‡,§] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | **Restricted to Specialist** | | | |
| Decompensated | | | | *Restricted to Specialist* |

| Table 3[†] | | | | |
|---|---|---|---|---|
| **Genotype** | **Failed Treatment** | **Regimen** | **Duration** | |
| cirrhosis, any genotype | | | | |
| Mixed genotype | | | | *Restricted to Specialist* |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration; [‡]Weight based ribavirin; [§]Refer to FDA approved labeling for use in individuals with impaired renal function

**Sovaldi, Technivie, and Daklinza Criteria for Denial**: Same as listed above in the section for Treatment Naïve patients.

**Quantity Limit:**

Sovaldi – One 400 mg tablet per day (28 tablets/28 days)
Technivie – Two tablets once per day with food (56 tablets/28 days)
Daklinza – One tablet once per day in combination with sofosbuvir (28 tablets /28 days)

**Additional Considerations:**

- Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes.
- Combination treatment with ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

c. A question came up regarding treatment experienced polymorphism testing. That testing will be required to ensure no resistance exists.
d. Dr. Narus provided a copy of and discussed a CMS release which outlined CMS' guidance regarding putting unnecessary limitations on medications used to treat Hepatitis C. Dr. Narus made the proposal that these new treatment regimens be discussed and approved, as they expand coverage. More discussion will take place at the January meeting.
e. Discussion ensued regarding a way to ensure that the prescriber and patient knew the cost of these medications, as well as the consequences of failing to complete the full treatment course. This topic will be discussed further in January.
f. Committee Motion:

**Criteria for Approval: Treatment Naïve:**

1. Adult patient age ≥ 18 years old; **AND**
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the

authorization request; **AND**

3. Meets diagnosis and disease severity of Hepatitis C, Genotype 2, 3, or 4 (GT 2, 3, or 4), and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. Agrees to complete regimen; **AND**
5. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); or any positive results are to be explained by prescriber; **OR**
   a. If the urine confirmation test is positive, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse; **AND**
6. If HCV/HIV co-infected, prescriber must provide documentation of CD4 count, HIV viral load, and regimen.

**Criteria for Renewal Authorization Approval, with Approval Duration:**

1. For regimens with durations longer than 12 weeks, HCV RNA must be submitted for treatment weeks 4 and 8; **AND**
2. HCV RNA < 25 IU/mL at treatment week 4; **OR**
3. The prescriber must maintain documentation in the patient's medical chart of the following information: HCV RNA level at treatment weeks 4 and 8, as well as HCV RNA levels after completion of therapy at week 12 post therapy (SVR12), and week 24 post therapy (SVR24). This information shall be made available upon request.
4. Based on HCV genotype and prior treatment experience
   - Refer to Table 1 for regimen durations; authorization duration will be approved as follows:

| Regimen Duration | Authorization Duration |
|---|---|
| 12 weeks | 12 weeks |
| 24 weeks | 12 weeks + 12 weeks* |

   *or under the discretion of Alaska Medicaid
5. Lost or stolen medication replacement requests will not be authorized.

**Regimen: Treatment Naïve:**

**Table 1**[†]

| Genotype | Regimen | Duration | |
|---|---|---|---|
| | | | **Exclusions** |
| GT 2<br>*Metavir F2-4* | sofosbuvir + ribavirin[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | | | **Exclusions** |
| GT 3<br>*Metavir F2-4* | sofosbuvir + ribavirin[‡,§*] | 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 3<br>*Metavir F2-4* | daclatasvir + sofosbuvir | 12 weeks | *Concomitant use with strong CYP3A inducer, severe renal impairment, ESRD* |
| | | | |
| GT 4<br>*Metavir F2-4, Child-Pugh A,* | Technivie + ribavirin[‡,§*] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and* |

| Table 1[†] | | | |
|---|---|---|---|
| **Genotype** | **Regimen** | **Duration** | |
| *treatment naïve* | | | *C), pregnancy* |
| GT 4<br>*Metavir F2-4* | sofosbuvir + ribavirin[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4* | sofosbuvir + ledipasvir | 12 weeks | |
| GT 4<br>*Metavir F2-4, Child-Pugh A, treatment naïve, cannot take or tolerate ribavirin* | Technivie[‡] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C)* |
| | | | |
| GT 5 or 6<br>*Metavir F2-4* | sofosbuvir + ledipasvir | 12 weeks | |
| | | | |
| GT 2,3,4<br>*Hepatocellular carcinoma awaiting liver transplantation AND Meets Milan criteria: In single hepatocellular (HC) carcinomas, tumor ≤ 5 cm in diameter, OR In multiple HC carcinomas, no more than 3 tumor nodules, each ≤ 3 cm in diameter, AND No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.* | sofosbuvir + ribavirin[‡,§*] | 48 weeks *or until liver transplant* | *Severe renal impairment, ESRD; pregnancy* |
| **Restricted to Specialist** | | | |
| GT 2, 3, 4, 5, 6<br>*decompensated cirrhosis* | | | *Restricted to Specialist* |
| Mixed genotype | | | *Restricted to Specialist* |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration;
[‡]Weight based ribavirin; [§]Refer to FDA approved labeling for use in individuals with impaired renal

function. [*]If ribavirin is not used as part of the regimen indicated, Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized.

**Sovaldi, Technivie, and Daklinza Criteria for Denial:**

1. Patient is not abstaining from the use of illicit drugs and alcohol as evidenced by submitted urine confirmation test results, without documentation submitted that the patient is actively attending a treatment program for substance abuse.
2. Diagnostic/disease severity evidence is not submitted with the request.
3. HCV RNA results not submitted with the request.
4. For regimens containing ribavirin, patient is pregnant or lactating.
5. HCV genotype is 1a or 1b (refer to respective criteria).

| Table 2: Additional Criteria for Denial[†] | | | | |
|---|---|---|---|---|
| Sovaldi | Severe renal impairment (eGFR < 30 mL/ min/ 1.73m$^2$) or end stage renal disease (ESRD) requiring hemodialysis | Child-Pugh score greater than 6 [class B or C] and treatment is not being managed by a liver disease specialist | Taking a concomitant drug that has a significant clinical interaction or is contraindicated | Genotype 5 or 6 infection |
| Technivie | Moderate to severe hepatic impairment: Child-Pugh score greater than 6 [class B or C] | Taking a concomitant drug that has a significant clinical interaction or is contraindicated with any of the agents (e.g., highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious events, or drugs that are moderate or strong inducers of CYP3A) | Co-infection with HIV-1, without a current suppressive antiretroviral drug regimen | Genotype 1, 2, 3, 5 or 6 infection |
| Daklinza | Concomitant use with a drug that strongly induces CYP3A | Presence of a NS5A Y93H polymorphism | Genotype 1, 2, 4, 5 or 6 infection | |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration

**Criteria for Approval: Treatment Experienced/Retreatment Patients:**

1. Adult patient age ≥ 18 years old; **AND**
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the authorization request; **AND**
3. Meets diagnosis and disease severity of Hepatitis C, Genotype 2, 3, or 4 (GT 2, 3, or 4), and Metavir Fibrosis score F2-F4 equivalent; **AND**
4. Agrees to complete regimen; **AND**

5. For patients previously treated with an NS5A inhibitor, NS5B inhibitor or a NS3/4a protease inhibitor, polymorphism testing results MUST be submitted; **AND**
6. If HCV/HIV co-infected, must provide documentation of CD4 count, HIV viral load, and regimen; **AND**.
7. Documentation of previously trialed HCV therapies, dates of therapy, whether full therapy was completed or discontinued early, and, if discontinued early, the reason for the discontinuation is included in the authorization request; **AND**
8. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); or any positive results are to be explained by prescriber; **OR**
    b. If the urine confirmation test is positive, the prescriber must submit documentation that the patient is actively attending a treatment program for substance abuse.

**Regimen: Treatment Experienced:**

| Table 3[†] | | | | |
|---|---|---|---|---|
| **Genotype** | **Failed Treatment** | **Regimen** | **Duration** | |
| | | | | **Exclusions** |
| GT 2<br>*Metavir F2-4* | Peg-interferon + ribavirin | Sofosbuvir + ribavirin[‡,§*] | 16 weeks OR 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 2<br>*Metavir F2-4* | Peg-interferon + ribavirin | Sofosbuvir + ribavirin+ Peg-interferon[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | | | | **Exclusions** |
| GT 3<br>*Metavir F2-4* | | Sofosbuvir + daclatasvir + ribavirin [‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy, Concomitant use with strong CYP3A inducer* |
| | | | | **Exclusions** |
| GT 4<br>*Metavir F2-4* | Sofosbuvir +/- ribavirin +/- peg-interferon | sofosbuvir + ledipasvir+ ribavirin[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4, Child-Pugh A* | Sofosbuvir +/- ribavirin +/- peg-interferon | paritaprevir + ombitasvir + ritonavir + ribavirin[‡,§*] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C), pregnancy* |
| GT 4<br>*Metavir F2-4* | Simeprevir + ribavirin, + peg-interferon<br>OR<br>Sofosbuvir + simeprevir<br>OR<br>Ritonavir + paritaprevir + | sofosbuvir + ledipasvir+ ribavirin[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |

| Table 3[†] | | | | |
|---|---|---|---|---|
| **Genotype** | **Failed Treatment** | **Regimen** | **Duration** | |
| | ombitasvir | | | |
| GT 4<br>*Metavir F2-4, Child-Pugh A* | Peg-interferon + ribavirin | paritaprevir + ombitasvir + ritonavir + ribavirin[‡,§*] | 12 weeks | *Moderate to severe hepatic impairment (Child-Pugh B and C), pregnancy* |
| GT 4<br>*Metavir F2-4* | Peg-interferon + ribavirin | sofosbuvir + ribavirin[‡,§*] | 24 weeks | *Severe renal impairment, ESRD; pregnancy* |
| GT 4<br>*Metavir F2-4* | Peg-interferon + ribavirin | sofosbuvir + ledipasvir | 12 weeks | |
| | | | | |
| GT 5 or 6<br>*Metavir F2-4* | | sofosbuvir + ledipasvir + ribavirin[‡,§*] | 12 weeks | *Severe renal impairment, ESRD; pregnancy* |
| | **Restricted to Specialist** | | | |
| Decompensated cirrhosis, any genotype | | | | *Restricted to Specialist* |
| Mixed genotype | | | | *Restricted to Specialist* |

[†]Prescribers are advised to review FDA approved labeling and other available clinical resources when determining appropriate regimens based on contraindications and warnings including clinically relevant drug-drug and drug-disease interactions as well as considerations for HIV/HCV co-infected individuals to ensure appropriate monitoring schema are taken into consideration; [‡]Weight based ribavirin; [§]Refer to FDA approved labeling for use in individuals with impaired renal function. * If ribavirin is not used as part of the regimen indicated, Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized.

**Sovaldi, Technivie, and Daklinza Criteria for Denial:** Same as listed above in the section for Treatment Naïve patients.

**Criteria for Retreatment Renewal Authorization Approval, with Approval Duration:**

1. For retreatment regimens with durations longer than 12 weeks, HCV RNA must be submitted for retreatment weeks 4 and 8; **AND**
2. HCV RNA < 25 IU/mL at treatment week 4; **OR**
3. The prescriber must maintain documentation in the patient's medical chart of the following information: HCV RNA level at retreatment weeks 4 and 8, as well as HCV RNA levels after completion of therapy at week 12 post therapy (SVR12), and week 24 post therapy (SVR24). This information shall be made available upon request.
4. Based on HCV genotype and prior treatment experience
   - Refer to Table 1 for regimen durations; authorization duration will be approved as follows:

| Regimen Duration | Retreatment Authorization Duration |
|---|---|
| 12 weeks | 12 weeks |
| 16 weeks | 12 weeks + 4 weeks |
| 24 weeks | 12 weeks + 12 weeks* |

*or under the discretion of Alaska Medicaid

a. Lost or stolen medication replacement requests will not be authorized.

**Quantity Limit:**

Sovaldi – One 400 mg tablet per day (28 tablets/28 days)
Technivie – Two tablets once per day with food (56 tablets/28 days)
Daklinza – One tablet once per day in combination with sofosbuvir (28 tablets /28 days)

**Additional Considerations:**

- Ongoing patient engagement is encouraged throughout the treatment course for optimal outcomes.
- Combination treatment with ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

Passed Unanimously

2. Kalydeco
    a. Dr. Wall discussed changes in the product labeling since the Committee's last review.
    b. Proposed criteria:
        i. Criteria for Approval:
            1. Diagnosis of Cystic Fibrosis; **AND**
            2. Confirmed *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R* mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene from an FDA-cleared CF mutation test; **OR**
            3. If lab results from the patient's CF mutation test are not available, provide documentation relating to how the prescriber knows that the patient has one of the *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or* R117H mutations; **AND**
            4. Recipient is 2 years of age or older; **AND**
            5. Is not being used concomitantly with strong CYP3A inducers; **AND**
            6. Is not being used concomitantly with strong CYP3A inhibitors without dose adjustment to compensate for the interaction.
        iv. Criteria for Denial
            1. Homozygous for the *F508del* mutation in the *CFTR* gene; **OR**

2. No confirmed diagnosis of Cystic Fibrosis; **OR**
3. Patient is less than 2 years of age; **OR**
4. Is being used concomitantly with strong CYP3A inducers; **OR**
5. Is being used concomitantly with strong CYP3A inhibitors without dose adjustment to compensate for the interaction.

v. Length of Authorization:
1. Initial coverage may be approved for 2 months.
2. Re-authorization may be approved for up to 10 months if documentation of clinical improvement submitted

vi. Quantity Limit: Maximum 2 doses per day; 30 days

c. Committee motion:

i. Criteria for Approval:
1. Diagnosis of Cystic Fibrosis, accompanied with results from a positive sweat test; **AND**
2. Confirmed *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R* mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene from an FDA-cleared CF mutation test; **OR**
3. If lab results from the patient's CF mutation test are not available, provide documentation relating to how the prescriber knows that the patient has one of the *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or* R117H mutations; **AND**
4. Recipient is 2 years of age or older; **AND**
5. Is not being used concomitantly with strong CYP3A inducers; **AND**
6. Is not being used concomitantly with strong CYP3A inhibitors without dose adjustment to compensate for the interaction.

ii. Criteria for Denial
1. Homozygous for the *F508del* mutation in the *CFTR* gene; **OR**
2. No confirmed diagnosis of Cystic Fibrosis; **OR**
3. Patient is less than 2 years of age; **OR**
4. Is being used concomitantly with strong CYP3A inducers; **OR**
5. Is being used concomitantly with strong CYP3A inhibitors without dose adjustment to compensate for the interaction.

iii. Length of Authorization:
1. Initial coverage may be approved for 2 months.

2. Re-authorization, may be approved for up to 10 months if documentation of clinical improvement submitted

d. Quantity Limit: Maximum 2 doses per day; 30 days

Pending approval and consult with pulmonology specialist.
Passed Unanimously

(5) Past Intervention Informational Updates
(6) FDA/DEA Updates
    a. FDA Drug Safety Communications
        i. Entacapone [10/26/2015]
        ii. Viekira & Technivie [10/22/2015]: Dr. Wall discussed the warning that these products may cause liver injury, particularly in patients with underlying liver disease.
        iii. Kayexalate [10/22/2015]
        iv. Avycaz [9/22/2015]
        v. Tramadol [9/21/2015]: FDA is investigating the use of tramadol in kids <17 causing breathing difficulty and possibly death. This side effect is due to an ultra rapid metabolizer.
        vi. Clozapine [9/15/2015]: All REMS programs have merged into a single program.
        vii. Canagliflozin [7/30/2015]
(7) FAERS Report
(8) Quality Measure
(9) Retrospective Review
    a. Extended-release opioids
        i. There are concerns related to the abundance of opioids being prescribed for short-term use. Data were pulled for large quantities of oxycodone 5 solution. A trend was identified for members ranging from age 4-18 years getting prescriptions for 350-500 mLs of oxycodone post-operatively for relatively minor surgeries.
        ii. Discussion around the best way to ensure reasonable quantities of opioids took place.
        iii. Recommendation was to continue the PA and add a QL to the medication. A QL of 120 mL of oxycodone solution will be added for pediatrics without cancer pain. More research will be done before a QL will be added to adults.
(10) Standing Reviews
(11) End of Public Meeting

Meeting adjourned at 3:41pm
**Next Meeting**: January