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DEPARTMENT OF JUSTICE
TRIAL DIVISION

MEMORANDUM

DATE: January 6, 2017

TO: Beth Englander
Marisa Samuelson
Stephen S. Walters
Oregon Law Center

Kevin Costello
Center for Health Law & Policy Innovation
Harvard Law School

FROM: Renee Stineman, Attorney-In-Charge
Special Litigation Section

SUBJECT: Updated Memorandum of Understanding between Oregon Health Authority (OHA) and Oregon Law Center and Center for Health Law & Policy Innovation (collectively, OLC)

OHA is committed to prioritizing essential services and considers expansion of coverage for Hepatitis C (HCV) treatment to be an important priority for Oregonians. Currently, OHA's coverage criteria for Oregon Health Plan (OHP) authorizes treatment of stage F3 and F4 HCV disease, with limited coverage of some stage F2 disease (such as patients who are also HIV-positive or have had a liver transplant). Newly developed, direct acting anti-viral medications (DAAs) have significantly increased the cost of HCV treatment. OHA has spent over $95.5 million on treating HCV at this coverage level since release of the DAAs. The agency's and the Governor's proposed budgets reflect the desire to expand HCV treatment to all Oregon Health Plan (OHP) members with stage F2 stage of the disease by January 1, 2018, if the budgets are funded to the requested levels.

The OLC and CHLPI have threatened to file a lawsuit against OHA alleging that the agency's current coverage criteria for OHP for HCV treatment violates federal Medicaid law. OHA admits no liability relating to the proposed lawsuit.

The agency has a process for establishing prioritization of essential services, and in accordance with that process, the agency plans to expand coverage of HCV, as outlined in this Memorandum of Understanding.

In furtherance of OHA's plan for expanding OHP coverage for HCV treatment, OHA will:

1. Expand coverage to all OHP members for HCV treatment with HCV stage F-2 by January 1, 2018, conditioned on funding by the Oregon legislature in the 2017 legislative session;

2. Not seek re-prioritization of HCV treatment by F-scores on the Prioritized List;

3. Advocate for legislative approval of funding in the 2017 legislative session in line with OHA's Policy Option Package;

4. Continue to ensure its Coordinated Care Organization (CCO) coverage criteria are properly aligned with Oregon's Fee for Service (FFS) criteria for HCV/DAA coverage. For example, OHA has developed and included within the current CCO contracts a risk corridor that requires CCOs to use the exact FFS criteria. The risk corridor incentivizes CCOs to comply with this requirement through funding agreements.

5. Increase communication with HCV advocates and OLC by providing quarterly summaries of reported data on the number of DAA treatments provided to any OHP member reporting during the immediately prior quarter, broken down between CCO and FFS, in a form to be developed by OHA. The reporting will begin 30 days after the close of the second quarter of 2017 and the first report will cover the first quarter of 2017. In addition, OHA will agree to explore ways to develop a system to efficiently and accurately collect data on denial of DAA treatment coverage and to implement such a system within one year;

6. OHA agrees to receive bi-monthly quarterly updates from OLC on OHP members who are denied HCV treatment and take action when appropriate, as determined by OHA. Reports should be provided by email to Heather Johnson, at heather.n.johnson@dhsoha.state.or.us and Rhonda Busek, at rhonda.j.busek@state.or.us ;

7. Continue to take reasonable steps to ensure CCOs comply with contractual and legal obligations to avoid inappropriate barriers to treatment, including but not limited to, monitoring CCO denials for DAA treatment upon completion of the denial data collection system described in paragraph 5 above;

8. Perform a mid-2017 review of expenditures for HCV treatment to inform OHA in considering possible reinvesting funding previously allocated for HCV treatment but not spent for further expansion of HCV coverage in 2018 and, upon completion, report to OLC any decisions by OHA resulting from that review;

9. Modify its prior authorization criteria to conform to the MOU in not more than 90 days per paragraph 9 and again in not more than 9 months per paragraph 10 (draft attached hereto as Appendix A) as soon as reasonably practicable (providing a copy of these modifications to OLC) as follows, which is anticipated to take 60 to 90 days, but no more than 90 days, from execution of this MOU to implement through rule changes:

a. Reduce required proof of life expectancy from 5 years or more to 1 year or more;

b. Remove specialists restriction for F0, F1, F2 and F3 DAA prescribing. For F3 only, specialist restriction will be removed only for that period from when the member has sought treatment by a specialist and when the member begins receiving treatment by a specialist, so as not to delay DAA treatment while a member is waiting for a specialist to become available;

c. Implement a standard for members with test results that show an F score range (ie: between F2 and F-3) that either (1) requires application of the highest F score in the range for determining coverage (for example, if a member's test result shows an F score of between F-2 and F-3, the member will be considered to have stage F-3 for purposes of coverage) or (2) require one additional, more specific, testing of an individual, if the higher stage is not applied for lack of specificity, however, additional testing may not be limited to biopsy (e.g. coverage cannot be contingent on member consenting to biopsy) and must include the option of noninvasive testing, such as elastography. Any resulting additional testing will not count against limits on number of covered testing per year. After one additional test, if a range still exists, the highest F score in the range will apply for determining coverage; and

d. OHA will distribute educational materials or other training to providers on HVC treatment and prior authorization criteria upon implementation of these modifications.

10. Expand the prior authorization criteria for HCV treatment as follows, which is anticipated to take approximately 6 to 9 months, but no more than 9 months, from execution of this MOU to implement:

a. To apply criteria currently in place for stage F-2 disease to stage F-1 and F-0 disease for OHP members who are co-infected with HIV,

b. To include coverage for members able to provide sufficient documentation of labs or biopsy showing fast progressing fibrosis that would require treatment earlier than the approved fibrosis stage. Determination of the definition of fast progressing fibrosis will be made consistent with guidance by the Health Evidence Review Commission or Pharmacy and Therapeutics Committee, whichever OHA determines is the appropriate forum to consider the matter. In this process, OHA agrees to obtain and consider input from experts in the area of HCV treatment, including

Dr. Benner. OHA will have this matter considered by the appropriate forum during the calendar year 2017 and will implement the changes during the 2018 calendar year, contingent on adequate funding; and

c. To provide coverage for additional extrahepatic manifestations and/or comorbidities consistent with guidance by the Health Evidence Review Commission or Pharmacy and Therapeutics Committee, whichever OHA determines is the appropriate forum to consider the matter. In this process, OHA agrees to obtain and consider input from experts in the area of HCV treatment, including Dr. Benner. OHA intends to have this matter considered by the appropriate forum during the calendar year 2017 with the goal of implementation during the 2018 calendar year, contingent on adequate funding.

11. Perform a mid-2018 review of expenditures for HCV treatment to inform OHA in considering the possibility of expanding to F-0 in the next biennium budget request and, upon completion, report to OLC any decisions by OHA resulting from that review.

OHA commits to make good faith efforts to accomplish the above-described changes and results. However, this memorandum shall not be enforceable in court and does not constitute a contract or other enforceable promise.

OHA's commitment to these aims includes a commitment to take reasonable steps to obtain funding, where needed, from the Oregon Legislative Assembly to accomplish this plan. If adequate funding is not authorized, OHA will assess which of these goals, if any, it will pursue. While OHA welcomes comment and cooperation from OLC, OHA maintains that it has ultimate discretion to determine the time and the manner in which the above-described changes and results are pursued.

OLC understands this memorandum to reflect OHA's intent. In support of that intent, OLC and CHLPI's current clients intend to refrain from filing a lawsuit pending the outcome of the 2017 legislative process and OHA's compliance with this MOU. OLC's clients may pursue litigation if the agency does not receive the funding it has requested on which the above commitments are predicated, or at any time before or after the conclusion of the 2017 session if the commitments expressed in this MOU are not followed.

The provisions of this memorandum are understood to apply from January 10, 2017, to the end of the next biennium (June 30, 2019).

Oregon Law Center and CHLPI Clients

Oregon Health Authority

Lynne Saxton

Lynne Saxton, Director

Date: 3-14-17

Hepatitis C Direct-Acting Antivirals

Goals:

- ☐ Approve use of cost-effective treatments supported by the medical evidence.
- ☐ Provide consistent patient evaluations across all hepatitis C treatments.
- ☐ Ensure appropriate patient selection based on disease severity, genotype, and patient comorbidities.

Length of Authorization:

- ☐ 8-12 weeks

Requires PA:

- ☐ All direct-acting antivirals for treatment of Hepatitis C

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of chronic Hepatitis C infection?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness.
3. Is expected survival from non-HCV-associated morbidities more than 1 year?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness.
4. Has all of the following pre-treatment testing been performed: a. Genotype testing in past 3 years; b. Baseline HCV RNA level in past 6 months; c. Current HIV status of patient d. Current HBV status of patient e. Pregnancy test in past 30 days for a woman of child-bearing age; and f. History of previous HCV treatment and outcome? Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis.	Yes: Record results of each test and go to #5	No: Pass to RPh. Request updated testing.

Approval Criteria		
5. Has the patient failed treatment with <u>any</u> of the following HCV NS5A inhibitors: a) Daclatasvir plus sofosubvir; b) Ledipasvir/sofosbuvir; c) Paritaprevir/ritonavir/ombitasvir plus dasabuvir; d) Elbasvir/grazoprevir; <u>or</u> e) sofosbuvir/velpatasvir)? <u>Note</u>: Patients who failed treatment with sofosbuvir +/- ribavirin or pegylated interferon can be retreated (see table below).	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: If urgent retreatment is needed, resistance testing must be done to indicate susceptibility to prescribed regimen. Refer to medical director for review.	**No:** Go to #6
6. Which regimen is requested?	Document and go to #7	
7. Does the patient have HIV coinfection and is under treatment by a specialist with experience in HIV?	**Yes:** -If patient has Metavir fibrosis stage F0-F2; Go to #9 -If patient has Metavir fibrosis stage F3-F4 or evidence of cirrhosis: Go to #13	**No:** Go to #8

Approval Criteria		
8. Does the patient have: Liver biopsy, imaging test (transient elastography [FibroScan®], acoustic radiation force impulse imaging [ARFI], or shear wave elastography [SWE]), or serum test if the above are not available (enhanced liver fibrosis [ELF]; Fibrometer; FIBROSpect II) to indicate fibrosis (METAVIR F2)?	**Yes:** Go to #9 Note: Other imaging and blood tests are not recommended based on evidence of poor sensitivity and specificity compared to liver biopsy For elastography results falling in a range (e.g. F2 to F3), fibrosis stage should be rounded up and categorized as the higher F stage for the purpose of treatment. If elastography is not available, and serum test results fall in a range, additional testing should be obtained to determine more specifically the stage of fibrosis..	**No:** Go to #10
9. **Is the regimen prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist with experience in treatment of Hepatitis C? OR** A provider knowledgeable in treating Hepatitis C?	**Yes:** Go to #14	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
10. Does the patient have: a) A biopsy, imaging test (transient elastography [FibroScan®], acoustic radiation force impulse imaging [ARFI], or shear wave elastography [SWE]) to indicate advanced fibrosis (METAVIR F3) or cirrhosis (METAVIR F4); or b) Clinical, radiologic or laboratory evidence of complications of advanced cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma)?	**Yes:** Go to #13 Note: Other imaging and blood tests are not recommended based on evidence of poor sensitivity and specificity compared to liver biopsy For elastography results falling in a range (e.g. F2 to F3), fibrosis stage should be rounded up and categorized as the higher F stage for the purpose of treatment. If elastography is not available and serum test results fall in a range, additional testing should be obtained to determine more specifically the stage of fibrosis.	**No:** Go to #11
11. Does the patient have one of the following extrahepatic manifestations of Hepatitis C (with documentation from a relevant specialist that their condition is related to HCV)? a) Type 2 or 3 cryoglobulinemia with end-organ manifestations (i.e., leukocytoclastic vasculitis); or b) Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; or c) Porphyria cutanea tarda	**Yes:** Go to #13	**No:** Go to #12
12. Is the patient in one of the following transplant settings: a) Listed for a transplant and treatment is essential to prevent recurrent hepatitis C infection post-transplant; or b) Post solid organ transplant?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
13. Is the regimen prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist with experience in treatment of Hepatitis C?	**Yes:** Go to #14	**No:** Pass to RPh. Deny; medical appropriateness. Forward to DMAP for further manual review to determine appropriateness of prescriber.
14. In the previous 6 months: ☐ Has the patient actively abused alcohol (>14 drinks per week for men or >7 drinks per week for women or binge alcohol use (>4 drinks per occasion at least once a month); OR ☐ Has the patient been diagnosed with a substance use disorder; OR ☐ Is the prescriber aware of current alcohol abuse or illicit injectable drug use?	**Yes:** Go to #15	**No:** Go to #16
15. Is the patient enrolled in a treatment program under the care of an addiction/substance use treatment specialist?	**Yes:** Go to #16	**No:** Pass to RPh. Deny; medical appropriateness.
16. Will the patient and provider comply with all case management interventions and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness.
17. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; <u>or</u> b) Daclatasvir + sofosbuvir for GT 3 infection?	**Yes:** Go to #18	**No:** Go to #19
18. Has the patient had a baseline NS5a resistance test show a resistant variant to one of the agents in #16?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #16

Approval Criteria		
19. Is the prescribed drug regimen a recommended regimen based on the patient's genotype and cirrhosis status (see Table 1)?	**Yes:** Approve for 8-12 weeks based on duration of treatment indicated for approved regimen	**No:** Pass to RPh. Deny; medical appropriateness.