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MEMORANDUM

MEMO NOS.

QI-1614

FFS 16-04

TO: Medicaid Fee-For-Service (FFS), QUEST Integration (QI) Health Plans,
Physicians and Pharmacies

FROM: *Uet*
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SUBJECT: DIRECT ACTING ANTIVIRAL (DAA) MEDICATIONS FOR TREATMENT OF CHRONIC
HEPATITIS C INFECTION

The treatment of chronic hepatitis C virus (HCV) infection is rapidly changing with nine DAA medications receiving Food and Drug Administration (FDA) approval within the past three years (Appendix A).

Health plans must continually update policies for new FDA approved therapies and monitor FDA warnings in this rapidly changing field of DAA therapies. This memorandum serves as broad guidance for the treatment of chronic HCV. Health plans must also monitor warnings and contraindications for each DAA medication including drug-drug interactions and warnings regarding supplement use.

The QI health plans will cover DAA's for chronic HCV in patients who meet inclusion and exclusion criteria outlined below. Effective January 1, 2017, inclusion criteria will include patients with a metavir fibrosis score F1 or greater.

Treatment of chronic HCV with DAA medications may be covered when all of the following inclusion criteria are met (subject to limitations/exclusions):

- 1) Patient is at least 18 years of age. Current FDA approvals are limited to adults.
- 2) Treatment is in accordance with FDA approved treatment regimens.
- 3) Patient has chronic HCV infection and a baseline quantitative HCV ribonucleic acid (RNA) result within the previous three months of request for treatment.
- 4) Patient has chronic HCV with at least one of the following criteria:
 - a. Effective January 1, 2017, metavir fibrosis score of F1 or greater. Prior to January 1, 2017, metavir fibrosis score of F3 or greater or based on medical necessity.
 - b. Radiologic or clinical evidence of cirrhosis (e.g., evidence of portal hypertension, ascites, esophageal varices).
 - c. Extrahepatic manifestations of chronic HCV, such as cryoglobulinemia.
 - d. Patient is a candidate for liver transplantation.
 - e. Patient has chronic HCV induced renal disease.
 - f. Patient with history of chronic HCV and HIV may be treated at any stage due to potential accelerated progression of liver disease.
 - g. Healthcare worker with direct patient contact may be treated at any stage.
 - h. Women of childbearing age may be treated at any stage.
- 5) The medication is prescribed by, or in consultation with, one of the following specialists:
 - a. Hepatologist
 - b. Gastroenterologist
 - c. Infectious Disease Specialist
 - d. HIV specialist
- 6) Patient does not have alcohol or other substance abuse within the three months prior to treatment as evidenced by history and urine toxicology screen.
- 7) Prescribing physician attests that the patient is at low risk for non-compliance.
- 8) Patient demonstrates good compliance and agrees to the following:
 - a. 100% medication compliance.
 - b. Regular follow up with specialty pharmacy, treating providers, and laboratory blood draws, such as HCV RNA levels, when ordered.
 - c. No active alcohol or substance abuse.
 - d. Compliant with drug screening such as urine toxicology screen when ordered by provider.

- 9) **Medical conditions that may impact adherence, including mental health conditions and substance abuse, must be well controlled prior to starting treatment.**

DAA medications may be covered when all of the inclusion criteria specified previously are met (subject to limitations below). DAA medications may not be covered when any one of the following limitations/exclusions below is present:

- 1) **Chronic decompensated liver disease as defined by Child-Pugh > 6, with exception for a patient who is an active candidate for liver transplantation (Appendix B).**
- 2) **Hepatocellular carcinoma, with exception for a patient who is an active candidate for liver transplantation.**

Other considerations:

- 1) **Avoid concurrent use of medications or supplements that are FDA contraindicated.**
- 2) **Patients who have co-infection with HCV/HBV should have HBV well controlled prior to starting treatment.**
- 3) **Patients who have co-infection with HCV/HIV will require close follow up with an HIV or infectious disease specialist.**
- 4) **In patients who have a history of solid organ transplantation, treatment with DAA may be contraindicated and consultation with transplant center should occur prior to starting treatment.**
- 5) **Other life threatening medical conditions, such as metastatic cancer, should be treated and controlled prior to starting DAA therapy for chronic HCV.**

**Appendix A:
Food and Drug Administration Approved Direct Acting Antiviral Treatments for Chronic
Hepatitis C Virus Infection**

Table 1: FDA Approved DAA for the Treatment of Chronic Hepatitis C

Medication	FDA Approval Date
teleprevir (Incivek)	May 2011
boceprevir (Victrelis)	May 2011
simeprevir (Olysio)	November 2013
sofosbuvir (Sovaldi)	December 2013
sofosbuvir / ledipasvir (Harvoni)	October 2014
simeprevir / sofosbuvir (Olysio/Sovaldi)	November 2014
ombitasvir / paritaprevir / ritonavir with dasabuvir (Viekira Pak)	December 2014
daclatasvir (Daklinza)	July 2015
ombitasvir / paritaprevir (Technivie)	July 2015
elbasvir / grazoprevir (Zepatier)	January 2016
sofosbuvir / velpatasvir (Epclusa)	June 2016

**Appendix B:
Child-Pugh Score**

The Child-Pugh Score, also known as Child-Turcotte-Pugh (CTP) score, is a scoring system for severity of liver disease and likelihood of survival based on the presence of degenerative disease of the brain (encephalopathy), the escape or accumulation of fluid in the abdominal cavity (ascites), laboratory measures of various substances in the blood (see table below), and the presence of other co-existing diseases; after calculating the CTP score using a table similar to the one below, individuals can be classified into one of three categories:

- Childs A (5-6 points): 10 year survival 80-90%;
- Childs B (7-9 points): 5 year survival 60-80%; and
- Childs C (10-15 points): 2 year survival less than 50%.

Table 2: Child-Pugh Score

Variable	1 Point	2 Points	3 Points
Encephalopathy	None	Moderate	Severe
Ascites	None	Mild	Moderate
Albumin (mg/dL)	Greater than 3.5	2.8 – 3.5	Less than 2.8
Prothrombin time (International Normalized ratio) prolonged	Less than 4	4 – 6	Greater than 6
Bilirubin (mg/dL) Primary biliary cirrhosis Cirrhosis/primary Primary sclerosing cholangitis	1 – 4	4 – 10	Greater than 10
All other diseases	Less than 2	1 – 3	Greater than 3

Compensated liver disease: Child-Pugh score less than or equal to 6 (class A) in cirrhotic individuals before or during treatment.

Decompensated liver disease: Child-Pugh score greater than 6 (class B or class C) in cirrhotic individuals before or during treatment.

References:

- 1) American Association for The Study of Liver Disease Treatment (AASLD): Recommendations for Testing, Managing, and Treating Hepatitis C, updated on July 6, 2016. http://hcvguidelines.org/sites/default/files/HCV-Guidance_July_2016_b.pdf
- 2) Afdhal N, Reddy R, Nelson D, Lawitz E, Gordon S, Schiff E, et al. Ledipasvir and Sofosbuvir for previously treated HCV Genotype 1 Infection (ION2). N Engl J Med 2014; 370: 1483-93.
- 3) Afdhal N, Zeuzem S, Kwo P, Chojkier M, Gitlin N, Puoti M, et al. Ledipasvir and Sofosbuvir for Untreated HCV Genotype 1 infection (ION1). N Engl J Med 2014; 370:1889-98.
- 4) Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health (VA): Chronic Hepatitis C Virus Infection: Treatment Considerations, updated March 28, 2016. www.hepatitis.va.gov/provider/guidelines/2014hcv/index.asp
- 5) Food and Drug Administration. www.FDA.gov
- 6) Kowdley K, Gordon S, Reddy R, Rossaro L, Bernstein D, Lawitz E, et al. Ledipasvir and Sofosbuvir for 8 or 12 Weeks for Chronic HCV without Cirrhosis (ION3). N Engl J Med 2014; 370: 1879-88
- 7) Center for Disease Control, A Guide to Comprehensive Hepatitis C Counseling and Treatment, updated October 15, 2015. Accessed on August 24, 2016. <http://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf>