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MEMORANDUM

MEMO NO.

QI-1829

FFS 18-10

[Replaces QI-1721,
FFS 17-10]

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

FROM:  Judy Mohr Peterson, PhD
Med-QUEST Division Administrator

Curtis Toma, MD
Med-QUEST Division Medical Director

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

This memorandum is an update to QI-1721 and serves as broad guidance to the QI health plans for the treatment of chronic hepatitis C (HCV) infection. Treatment options for chronic HCV infection has rapidly expanded with several new DAA medications receiving Food and Drug Administration (FDA) approval in recent years (Appendix A).

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

- 1) Treatment is in accordance with FDA approved treatment regimens.
- 2) Patient has chronic HCV infection and a baseline quantitative HCV ribonucleic acid (RNA) result within the previous three months of request for treatment.

- 3) Patients with chronic HCV can be treated at any stage. The previous restriction of having a metavir fibrosis score of F1 or greater has been removed.
- 4) 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, and/or
 - e. Primary care physicians with expertise in the treatment of hepatitis C who are approved by the health plan.
- 5) Prescribing physician attests that the patient is compliant with treatment. Evaluation of compliance should consider alcohol use and urine toxicology results, among other factors. Patient should demonstrate good compliance with medications and appointments such as with specialty pharmacy, providers, and laboratory blood draws.
- 6) Medical conditions that may impact adherence, including mental health conditions and substance abuse, should be addressed prior to starting treatment.

Other considerations:

- 1) Avoid concurrent use of medications or supplements that are FDA contraindicated.
- 2) Other life threatening medical conditions, such as metastatic cancer, should be addressed prior to starting DAA therapy for chronic HCV.
- 3) Patients requiring highly specialized care, including but not limited to any one of the conditions below, should have DAA treatment directed by or in collaboration with a hepatologist or transplant facility.
 - a. Decompensated cirrhosis
 - b. Hepatocellular carcinoma
 - c. Candidate for liver transplantation
 - d. Candidate for other solid organ transplantation
 - e. History of solid organ transplantation
 - f. Coinfection with hepatitis B
 - g. Coinfection with HIV
- 4) Sobriety restrictions have been removed. Alcohol use and substance abuse are not absolute contraindications to DAA therapy.

Please contact Dr. Curtis Toma, Medical Director, at (808) 692-8106 or via e-mail at ctoma@dhs.hawaii.gov should you have any questions.

Attachment

Appendix A

Food and Drug Administration Approved Direct Acting Antiviral Treatments for Chronic Hepatitis C Virus Infection

Medication	FDA Approval Date
teleprevir (Incivek)	May 2011
boceprevir (Victrelis)	May 2011
simeprevir (Olyslo)	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
sofosbuvir / velpatasvir/voxilaprevir (Vosevi)	July 2017
glecaprevir / pibrentasvir (Mavyret)	August 2017

References:

- 1) American Association for The Study of Liver Disease Treatment (AASLD): Recommendations for Testing, Managing, and Treating Hepatitis C, updated on September 21, 2017. <http://hcvguidelines.org>; accessed December 18, 2018.
- 2) Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis and Related Conditions Program in the Office of Specialty Care Services: Chronic Hepatitis C Virus Infection: Treatment Considerations, updated August 27, 2018. <https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp>; accessed December 18, 2018.
- 3) Food and Drug Administration. www.FDA.gov; accessed December 18, 2018.