State of California—Health and Human Services Agency
Department of Health Care Services

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CCS Information Notice: 15-04 (Revised)

TO: ALL LOCAL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS) PROGRAM AND GENETICALLY HANDICAPPED PERSONS PROGRAM (GHPP) STAFF, CCS PROGRAM MEDICAL CONSULTANTS, COUNTY MEDICAL STAFF, AND SYSTEMS OF CARE DIVISION (SCD) STAFF

SUBJECT: RESTRICTION OF SPECIFIC HEPATITIS C THERAPY

The purpose of this revised Information Notice is to advise you that specific drugs used for the treatment of Hepatitis C are covered under the CCS Program and the GHPP as restricted drugs and to inform you that the California Department of Health Care Services (DHCS) has published a policy on chronic Hepatitis C treatment, effective July 1, 2015. CCS County staff and Medical Consultants should consult DHCS policy prior to reviewing any Service Authorization Request (SAR) for Hepatitis C drug treatment. The policy can be found within the website:

http://www.dhcs.ca.gov/Pages/HepatitisC.aspx

The newly restricted drugs are:

- Sofosbuvir (Sovaldi)
- Ledipasvir/Sofosbuvir (Harvoni)
- Boceprevir (Victrelis)
- Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir (Viekira Pak)
- Simeprevir (Olysio)
- Telaprevir (Incivek)

The treatment of Hepatitis C by using these newly restricted drugs will follow the Medi-Cal Program guidelines as published in the Medi-Cal Provider manual or the Food and Drug Administration (FDA)-approved indication (when Medi-Cal guidelines are absent). The guidelines currently in place are as follows:

- Sofosbuvir: Restricted to use in the treatment of chronic Hepatitis C Virus (HCV) infection as a component of a combination antiviral treatment regimen in adults (18 years of age and older). Also restricted to 1) a maximum quantity of 28 tablets per dispensing; and 2) duration of therapy lasting up to 12 or 24 weeks from the dispensing date of the first prescription or duration of therapy lasting up to 48 weeks in patients with hepatocellular carcinoma awaiting liver transplantation.

- Ledipasvir/Sofosbuvir: Restricted to use in the treatment of chronic HCV infection in adults (18 years of age and older). Also restricted to 1) a maximum quantity of 28 tablets per dispensing; and 2) duration of therapy lasting up to 8, 12, or 24 weeks from the dispensing date of the first prescription.

- Boceprevir: Restricted to use in combination with peginterferon alfa and ribavirin for treatment of genotype 1 chronic HCV infection in adult patients (18 years of age and older) with compensated liver disease. In addition, patients must not have previously failed therapy with a treatment regimen that includes boceprevir or other HCVNS3/4A protease inhibitors. Also restricted to a maximum quantity of 336 capsules per dispensing and therapy lasting up to 44 weeks from the dispensing date of the first prescription.

- Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir: Restricted to use in the treatment of chronic Hepatitis C Virus (HCV) infection in adults (≥18 years of age). Also restricted to 1) a maximum quantity of 112 tablets per dispensing; and 2) duration of therapy lasting up to 12 or 24 weeks from the dispensing date of the first prescription.

- Simeprevir: (FDA approved indication) Treatment of genotype 1 chronic Hepatitis C (in combination with other antihepacivirals).

  **Limitations of use:** Not for use as monotherapy; when used in combination with peginterferon alfa and ribavirin, screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80k polymorphism is strongly recommended (if detected, consider alternative therapy); not recommended for use in patients in whom a simeprevir-containing regimen or another regimen containing HCV protease inhibitors has failed.

- Telaprevir: Restricted to use in combination with peginterferon alfa and ribavirin for the treatment of genotype 1 chronic HCV infection in adult patients (18 years of age and older) with compensated liver disease. In addition, patients must not have previously failed therapy with a treatment regimen that includes telaprevir or other HCV NS3/4A protease inhibitors. Also restricted to a maximum quantity of 168 tablets per dispensing and therapy lasting up to 12 weeks from the dispensing date of the first prescription.

In addition, as published in the Provider Manual:

> "Providers must provide documentation of baseline HCV-RNA level and HCV genotype. In addition, when applicable, providers must document relevant clinical information (i.e., failure of prior treatment, presence of cirrhosis, etc.) in support of medical necessity for duration of therapy. Failure to submit supporting documentation may delay authorization."

Updated criteria can be searched within the Medi-Cal Provider Manual.

Exceptions to the above criteria will be evaluated on a case-by-case basis in consultation with Systems of Care Medical Consultants.

If you have any questions, please contact Edan Lum, Pharm D., Pharmaceutical Consultant, at (916) 322-1543 or (510)-286-0708, or via e-mail at edan.lum@dhcs.ca.gov.

**ORIGINAL SIGNED BY LOUIS R. RICO**

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Systems of Care Division