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STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

G.H., PETITIONER, v. UNITED HEALTHCARE, RESPONDENT.	:	**ADMINISTRATIVE ACTION** **FINAL AGENCY DECISION** **OAL DKT. NO. HMA 16629-14**

As Director of the Division of Medical Assistance and Health Services, I have reviewed the record in this matter, consisting of the Initial Decision, the documents in evidence, the entire contents of the OAL case file, and Respondent's exceptions to the Initial Decision. Procedurally, the time period for the Agency Head to file a Final Decision in this matter was extended until June 25, 2015 pursuant to an Order of Extension.

Based upon my review of the record, I hereby REVERSE the Initial Decision ordering the provision of Sovaldi, Olysio and Ribapak. United Healthcare denied authorization, concluding that this three drug regimen is not medically necessary. For the reasons which follow, I agree with that decision.

Petitioner, G.H., is 59-years old and has Stage 1 Hepatitis C, a chronic viral infection. G.H. was initially treated with interferon. However, his physician discontinued use of the interferon after he had suicidal thoughts, which is a common side effect in patients with a history of depression. Thereafter, G.H's doctor prescribed the three drug regimen of Sovaldi, Olysio and Ribavirin. United Healthcare denied coverage based upon its prior authorization guidelines which authorize these drugs for patients with stage 3 or stage 4 Hepatitis C. The ALJ disagreed with United Healthcare's decision, concluding that G.H. has shown a medical necessity for the drugs and that it is his only treatment option. Initial Decision at page 5. Unfortunately, I must disagree that this three drug regimen is a medically necessary treatment that should be paid for by United at this point.

As set forth in the Initial Decision, "medically necessary services" are defined as:

> Services or supplies necessary to prevent, diagnose, correct, prevent the worsening of, alleviate, ameliorate, or cure a physical or mental illness or condition; to maintain health; to prevent the onset of an illness, condition, or disability; to prevent or treat a condition that endangers life or causes suffering or pain or results in illness or infirmity; to prevent the deterioration of a condition; to promote the development or maintenance of maximal functioning capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate to individuals of the same age; to prevent or treat a condition that threatens to cause or aggravate a handicap or physical deformity or malfunction, and there is no other equally effective, more conservative or substantially less costly treatment available or suitable for the enrollee. The services provided, as well as the treatment, the type of provider and the setting, are reflective of the level of services that can be safely provided, are consistent with the diagnosis of the condition and appropriate to the specific medical needs of the enrollee and not solely for the

> convenience of the enrollee or provider of service and in accordance with standards of good medical practice and generally recognized by the medical scientific community as effective. Course of treatment may include mere observation or, where appropriate, no treatment at all. Experimental services or services generally regarded by the medical profession as unacceptable treatment are deemed not medically necessary. Medically necessary services provided are based on peer-reviewed publications, expert pediatric, psychiatric, and medical opinion, medical/pediatric community acceptance . . . (emphasis added.) N.J.A.C. 10:74-1.4

United Healthcare's coverage criteria for direct-acting oral antiviral agents are based on consideration of published guidelines addressing the treatment for Hepatitis C. Specifically, the Infectious Disease Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) jointly published recommendations for hepatitis C management which states the following for the treatment of Genotype 1 hepatitis C infection: "In many instances, however, it may be advisable to delay treatment for some patients with documented early fibrosis stage (F0-2), because waiting for future highly effective, pangenotypic, direct acting agent combinations in interferon-free regimens may be prudent." The AASLD/IDSA's recommendations for when and in whom to initiate treatment state that:

> Treatment is recommended for patients with chronic HCV infection. Immediate treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients and patients with severe extrahepatic hepatitis C. Based on available resources, immediate treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C are given high priority.

Additionally, a May 2014 report prepared by the Center for Evidenced-based Policy at Oregon Health & Science University states on page 6 that in contrast to

where there is a rapid progression and an immediate need for treatment (e.g., acute leukemia or serious bacterial infections), hepatitis C is a slowly progressing disease.

The above studies support United's prior authorization guidelines that treatment with this three drug regimen is not medically necessary for someone, like Petitioner, with stage 1 fibrosis. Thus, United's guidelines for these drugs require a diagnosis of stage 3 or stage 4 fibrosis, which G.H. does not have. United Healthcare contends that the ALJ's decision "may have been predicated on the misconception that stage 1 fibrosis will develop into advanced liver disease". See United Healthcare's Exceptions at page 2. The current studies and guidelines support United's contention that the ALJ's assumption is not medically proven and Petitioner presented no medical evidence that this three drug regimen is necessary based upon his present health condition.

As I have said in prior Final Agency Decisions, in a more perfect world, G.H., as well as every other Medicaid beneficiary, would have any item which will improve his or her quality of life. With the arrival of more effective and better-tolerated direct-acting antiviral medications, it appears that more people with Hepatitis C are eligible for treatment. However, the practical limitations of the State's budgetary constraints require that it limit the items it provides to those that are medically necessary. The Division does not dispute that G.H. should receive the level and quality of care to which he is entitled, but argues, as it must, that the "countervailing public interest (is) in conserving the state's resources and its ability to fund other worthy public assistance programs." New

Jersey Association of Health Care Facilities et al. v. Gibbs, et al., 838 F. Supp. 881, 929 (D.N.J. 1993), aff'd 14 F.3d. 48 (3d Cir. 1992). There is no doubt that this is a case that evokes sympathy and a desire to assist in any way possible. Nonetheless, the Division is required to evaluate each and every request for assistance, and many must be denied. The Division is limited to approving services and items which are medically necessary, and that necessity has not been shown in this case.

I note that Gilead Sciences, Inc., the developer of Sovaldi, has created a Patient Assistance Program known as Support Path to assist eligible Hepatitis C patients access Sovaldi. I suggest that Petitioner contact the Support Path Patient Assistance Program at 1-855-769-7284.

THEREFORE, it is on this 5th day of June 2015,

ORDERED:

That the Administrative Law Judge's recommended decision to provide Petitioner with Sovaldi, Olysio and Ribavirin is hereby REVERSED.

Valerie J. Harr, Director
Division of Medical Assistance
and Health Services