Dr. Joe Parks
Director Department of Social Services MO HealthNet Division
615 Howerton Court
Jefferson City, Missouri 65109

Dear Dr. Parks

We are writing about Missouri's prior authorization criteria and its clinical edits for the new class of Hepatitis C drugs (Sovaldi, Harvoni and others). The current criteria are more restrictive than authorized by federal law and are inconsistent with recent guidelines from the American Association for the Study of Liver Disease. More importantly, they restrict access to drugs that actually **cure** Hepatitis C (thereby reducing expensive hospitalization and other treatment costs) and save lives. We welcome a conversation with you about these requirements and any Agency plans to revise its criteria in light of recent federal guidance and/or continuing developments across the country. We know that other states have significantly revised their practices as more information becomes known about these new drugs and how they fit within the statutory and regulatory scheme of the Medicaid program.

Missouri's criteria require a metavir fibrosis score of at least F2 for genotype 3, and of at least F3 for genotypes 1, 2, and 4. This requires a patient to sustain high levels of organ damage before becoming eligible for treatment with these medications. This is contrary to recent AASLD/IDSA recommendations, which suggest treatment for all patients with chronic Hepatitis C regardless of disease stage. Studies from AASLD/IAS have shown the new DAA's are very cost effective treating all metavir scores. While these drugs all have very high WAC prices Medicaid received very large discounts and large rebates which reduces the price per patient.

The Medicaid Act requires states to cover drugs for FDA-approved uses and medically accepted indications. FDA does not limit Hepatitis C drugs based on metavir score or disease stage. In addition, the Medicaid Act only allows a covered outpatient drug to be excluded for treatment of a specific disease or condition for an identified population if, based on the drug's labeling, ''the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary.

Recent CMS guidance expressed concern that "some states are restricting access to DAA HCV drugs contrary to statutory requirements in section 1927 of the Act," and pointed to state policies limiting treatment to beneficiaries with metavir fibrosis scores of F3 as an example of unreasonably restrictive access to drugs. Missouri's restrictive criteria violate these same statutory requirements.

What are the MO Health.Net Division's Plans to bring these Agency practices into compliance with federal law and CMS guidance?

Various parts of the Missouri guidelines are defined by previous treatments and are no longer required with the new DAA's. for example:

1. Required abstinence from alcohol and illicit drug use,
2. Required viral load progression for 24-week treatment course.
3. Missouri's criteria states ''week 12 results must be less than 25 IlJ/ mL Treatment is prescribed in 12 to 24 week intervals, Based on genotype. Studies have shown that some people with advanced disease may require more treatment (and expense) than those with less sever disease.
4. Pregnant women denied treatment. This only applies to the use of Ribavirin. There are no adverse effect of pregnancy with the new DAA's

Based on the CMS letter dated November 5, 2015 Medicaid Drug Rebate Program and the AASLD/IDSA guidelines for hepatitis C, We believe that you may be in violation of the law in many areas.

We are willing to assist the state in rewriting the requirements and provide lifesaving care for our citizens.

Sincerely,

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