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Pursuing Justice,
Strengthening Lives

January 13, 2016

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

Re: Authorization Criteria for Hepatitis C Drugs

Dear Dr. Parks,

We are writing to initiate a dialogue regarding 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 federal guidance.[1] 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.[2]

Required disease stage

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 a high level of organ damage before becoming eligible for treatment with these medications. This is contrary to recent AASLD/IDSA

[1] This letter raises our initial questions and concerns. It does not purport to be a comprehensive legal or medical analysis of the Agency's criteria. There are clearly other aspects of the Agency's criteria that warrant further examination but we wanted to highlight initial concerns and open a dialogue. For example, the prohibition on Olysio for people who have previously used an oral protease inhibitor, the restriction on treatment for people with genotypes 5 and 6, the limit on Olysio for individuals with Q90K polymorphism, the 7 day window for refills and 168-day lookback period for re-treating all raise questions

[2] Among the states that have abandoned or significantly revised their initial restrictive practices (which had included criteria comparable to Missouri's restrictions) are California, Connecticut, Pennsylvania, and the District of Columbia. We also understand that commercial insurers are expanding coverage and that United Health Care Anthem, Cigna, Aetna, and Humana have no fibrosis restrictions.

recommendations, which suggest treatment for all patients with chronic Hepatitis C regardless of disease stage.[3]

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.[4] 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 [. . .]."[5]

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.[6] Missouri's restrictive criteria violate these same statutory requirements.

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

Required abstinence from alcohol and illicit drug use

Missouri's criteria require a negative urine screen for the most current three months, and also require complete abstinence from alcohol and illicit drug use during treatment. HCV frequently coexists with misuse of alcohol and illicit drugs. In fact, misuse of alcohol and illicit drugs can accelerate liver disease progression, making those beneficiaries an especially high priority for treatment.

According to a recent article in the Annals of Internal Medicine, "Hepatitis C virus and alcohol act synergistically in causing more severe liver injury than seen with either disease alone. Persons with coexisting alcohol disorders are at a higher risk for HCV-related complications."[7] The same article goes on to assert that "a growing body of evidence shows that there is no justification for systemically withholding treatment" from people who inject drugs.[8] In addition, people who use illicit drugs are at an increased risk of spreading HCV through shared needle use.

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[3] Recommendations for Testing, Managing, and Treating Hepatitis C, American Association for the Study of Liver Diseases & Infectious Diseases Society of America, updated December 11, 2015 (available at: http://www.hcvguidelines.org/full-report-view).
[4] 42 U.S.C. §1396(r)(8)(k)(6).
[5] 42 U.S.C. §1396(r)(8)(d)(4)(C).
[6] CMS Release No. 172, For State Technical Contacts, November 5, 2015, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.
[7] Annals of Internal Medicine, Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States, p. 220-221.
[8] *Id.*

Recent CMS guidance also listed "a period of abstinence from drug and alcohol abuse as a condition for payment" as an example of a state restriction contrary to the statutory requirements of the Medicaid Act.[9] As noted earlier, the Medicaid Act requires states to cover drugs for FDA-approved uses and medically accepted indications and includes no exceptions for people based on their drug or alcohol use. As noted above, these drugs can be especially helpful for these individuals.

In addition, federal law and its implementing regulations prohibit diagnosis-based discrimination in Medicaid.[10] The requirement of abstinence from alcohol and drug use also likely violates other federal laws, including the Americans with Disabilities Act, the Rehabilitation Act and the discrimination prohibitions of the Affordable Care Act.[11]

Required "appropriate diagnosis"

Missouri's criteria list "lack of appropriate diagnosis" as one of the denial criteria, without elaboration. We are interested in learning more about this criterion and how it works in practice. Is this an attempt to restrict treatment to individuals who received their diagnosis from specific specialists? Depending on how this prohibition is applied, it could violate Medicaid law and regulations prohibiting discrimination based on diagnosis or condition, as well as the disability discrimination statutes referenced above.

Required viral load progression for 24-week treatment course

Missouri's criteria states "week 12 results must be less than 25 IU/mL if duration of treatment is 24 weeks." This requirement appears to have no allowance for a treating physician to make an individualized determination of medical necessity for the beneficiary patient undergoing treatment. This restriction violates federal law, which requires that the amount, duration, and scope of services be consistent with medical necessity.[12]

Therapy length capped

Missouri's criteria cap Hepatitis C drugs at 12 or 24 weeks, varying depending on the patient's disease stage and prior treatments. This requirement also appears to have no allowance for a treating physician to make an individualized determination of medical necessity for the beneficiary patient undergoing treatment. This restriction is again a violation of federal law, which requires that amount, duration, and scope of services be consistent with medical necessity and that "reasonable standards" be applied to covered Medicaid services.[13]

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[9] CMS Release No. 172, For State Technical Contacts, November 5, 2015, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.
[10] 42 U.S.C. § 1396a(a)(17), 42 C.F.R. §§ 440.230 and 440.240.
[11] 42 U.S.C. § 18116(a), 42 U.S.C. § 12131-12134 and 29 U.S.C. §794.
[12] 42 U.S.C. § 1396a(a)(17), 42 C.F.R. §440.230(d).
[13] 42 U.S.C. § 1396a(a)(17), 42 C.F.R §440.230(d).

Pregnant women denied treatment

Missouri's criteria list "pregnancy" as one of the denial criteria for all new HCV drugs. This exclusion of an entire category of beneficiaries does not allow for an individualized review of the particular beneficiary's medical needs. We believe this denial criteria may be based on the FDA label for Sovaldi, which recommends Sovaldi be combined with ribavirin or peginterferon alfa/ribavirin. However, it is only the adjunct drugs, not Sovaldi itself, which is contraindicated for pregnancy. In the case of a patient who is pregnant, her provider could potentially prescribe Sovaldi without the contraindicated adjuncts. However, the categorical exclusion of all pregnant women from treatment prevents physicians from making individualized determinations of each patient's specific medical needs. This exclusion is also a violation of federal Medicaid law.

"Fail First" Requirement

The requirement that all patients try and fail on Viekira Pak before gaining access to life-saving medications is also highly problematic. As stated earlier, 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 [. . .]. Failure to try a *less effective* drug is not an acceptable reason for denying access to the preferred, most effective (and life-saving) treatment for Hepatitis C.

Moreover, even if it were permissible to employ a "fail-first" policy in this instance, the State must allow exceptions to "fail first" when a beneficiary's doctor recommends a treatment besides Viekira Pak based on an individualized assessment of medical necessity.

Conclusion

As outlined above, Missouri's current criteria are problematic and raise significant concerns for our clients. We would like to work with the MO HealthNet Division as it revises its criteria in light of recent CMS guidance, continuing medical developments and inconsistencies with the federal Medicaid law. We welcome the opportunity to work with the state to improve its practices.

Very truly yours,

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