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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 172**

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term “medically accepted indication” as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

When establishing formularies, states must ensure compliance with the requirements in section 1927(d)(4), including the requirements of section 1927(d)(4)(C) of the Act. Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an identified population if, based on the drug's labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), 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 and there is a written explanation (available to the public) of the basis for the exclusion.

Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.

CMS is aware that, given the costs of these new DAA HCV drugs, states have raised concerns about the budgetary impact to their Medicaid programs and beneficiary access to needed care. The agency shares these concerns. However, the recent launch of multiple DAA HCV drugs in the marketplace is creating competition in this class that may result in downward pressure on the prices of these drugs. This competition may enhance the ability of states to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices for both their FFS and managed care programs, thereby reducing costs. CMS encourages states to take advantage of such opportunities.

To that end, manufacturers have a role to play in ensuring access and affordability to these medications. CMS has sent a letter to the manufacturers of these DAA HCV drugs, asking them to provide information regarding any value-based purchasing arrangements they offer for these drugs so that states might be able to participate in such arrangements.

Permissible Limitations to Medicaid Drug Coverage

CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4[1].

[1] The metavir scoring system is used to assess inflammation and fibrosis by histopathological evaluation of a liver biopsy of patients with hepatitis C. The stages, indicated by F0 through F4, represent the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis; a chronic degenerative liver disease state in which normal liver cells are damaged and are then replaced by scar tissue. For more information about liver fibrosis please read Ramon Batallar and David A. Brenner, Liver fibrosis Journal of Clinical Investigation. 2005 Feb 1; 115(2): 209–218 by visiting http://www.ncbi.nlm.nih.gov/pmc/articles/PMC546435/

Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types, like gastroenterologists, hepatologists, liver transplant specialists, or infectious disease specialists in order for payments to be provided for the drug.

While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes,[2] such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their coverage policies. These resources include pharmacy and therapeutics (P&T) committees, drug utilization review (DUR) boards, and comparative analysis of the costs to treat HCV patients in light of the efficacy of these newer regimens in terms of cure rates, when compared to those of preexistent therapies. Additionally, CMS notes the availability of guidelines for states to refer to regarding testing, managing, and treating HCV put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA), which can be found at http://www.hcvguidelines.org/full-report-view. CMS also suggests that states consider implementing programs that provide patients on HCV treatment with supportive care that will enhance their adherence to regimens, thereby increasing the success rates.

Coverage under Medicaid Managed Care Plans

CMS is also concerned that in many states, Medicaid managed care organizations (MCOs) or other managed care arrangements' conditions for payment for DAA HCV drugs appear to be more restrictive than coverage under the states' fee-for-service (FFS) programs. Furthermore, in states with multiple MCOs or arrangements, the conditions for payment for DAA HCV drugs often differ between various plans.

CMS reminds states that the drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements. As with their FFS program, states are urged to carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access. States have the option to include these drugs in the managed care contracts and capitation rates or to "carve out" the drugs used in the treatment of chronic HCV

[2] In accordance with section 1927(d)(5) of the Act, a state plan may establish a prior authorization program as a condition of coverage or payment for a covered outpatient drug; however, the program must provide responses by telephone or other telecommunication device within 24 hours of a request for prior authorization, and, except for those drugs restricted or excluded from coverage pursuant to section 1927(d)(2) of the Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

infections from managed care contracts and capitation rates and instead provide access to these drugs through FFS or other arrangements.

Consistent with the regulation at 42 CFR §438.210, services covered under Medicaid managed care contracts (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid. While managed care plans may place appropriate limits on DAA HCV drugs using criteria applied under the state plan, such as medical necessity, the managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.

CMS notes that managed care plans are permitted to use other utilization controls provided that the services, as controlled under the health plan's policies, can be reasonably expected to achieve their purpose. However, states should carefully monitor utilization controls and the HCV coverage policies of their managed care plans to ensure that the organizations are providing appropriate access to covered services and benefits consistent with 42 CFR §438.210.

CMS recognizes the challenges of defining policies in the face of new and innovative drug treatments. It will monitor the policies and conditions states impose for the coverage of DAA HCV drugs to ensure compliance with the requirements of the Act and access to effective, clinically appropriate, and medically necessary treatments for beneficiaries. CMS will monitor state compliance with their approved state plans, the statue, and regulations to assure that access to these medications is maintained.

CMS shares with states the common goal of ensuring access to quality care for Medicaid beneficiaries. Given the complexities that have arisen with the introduction of the DAA HCV drugs, CMS will continue to work with State Medicaid agencies to continue providing and improving care to persons infected with chronic HCV infections. If you have any questions, please contact John M. Coster, Ph.D., R.Ph., Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov.

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