Memo

Implications of Proposed Rule on Medicare Part D Protected Class

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I. Introduction

Since the implementation of Medicare Part D in 2006, six classes of drugs have been protected to ensure patients with certain chronic conditions would not face discrimination or interruptions accessing their drugs. As such, private insurance plans who participate in Part D are required to cover all immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic drugs. In November 2018, however, the Centers for Medicare and Medicaid Services (CMS) announced a proposed rule aimed at reducing prescription drug prices for Medicare beneficiaries. The rule includes three provisions that could compromise protection for drugs in the six classes. As proposed, Part D prescription drug plans could: (1) increase their use of utilization management practices such as step therapy and prior authorization for protected class drugs; (2) exclude a protected class drug from its formulary if the drug represents a new formulation of an existing drug; and (3) exclude a protected class drug if its price increases exceed a standard rate of inflation over a specified time period.

Antiretrovirals are unique among the protected classes in that they treat and prevent HIV, an infectious disease. In contrast, the other protected class drugs are indicated for non-communicable diseases. Therefore, access restrictions would have serious public health implications both for infected patients and those at risk of infection. At present, only half of patients with HIV have reduced viral loads, highlighting the need for strategies that facilitate, not restrict, treatment access. Adherence to antiretroviral therapy (ART) is necessary to reduce viral load and disease transmission. Accordingly, current treatment guidelines recommend the use of tailored and patient-centered treatment, which inherently requires comprehensive treatment options. This is especially true of patients with HIV who may be covered by Medicare Part D, as this population has a higher burden of comorbidities and other treatment considerations. Restricted access or increased cost of treatment may cause patients to stop adhering to their treatment regimen, impacting these patients’ ability to maintain low viral loads. Additionally, newer innovative HIV treatments provide extensive patient benefits such as reduced adverse events and the potential to improve adherence (single-tablet regimens). For example, tenofovir alafenamide (TAF), can reduce the risks of bone loss and renal toxicity, which is especially important for older patients with HIV. Further, it is provided in single-tablet regimens (STRs), which have been associated with better adherence than multi-tablet regimens (MTRs).

In this memo, we assess the potential impacts of the three Part D proposed rule provisions on patients with HIV. Analyses conducted for this memo are based on results from a previously-published model by Baumgardner et al., 2018, which estimated the impacts of restrictive formularies for patients with HIV. That study examined how restricting access among innovative ART (measured through a series of formulary access scenarios) would affect the occurrence and cost of adverse events, as well as deaths attributable to sub-optimal disease management. The most restrictive scenario required patients to stay on a tenofovir disoproxil (TDF) regimen for the duration of their care, whereas the open formulary scenario resulted in a substantial number of patients initiating treatment on the more recently introduced TAF therapy, allowed for switching of patients to TAF therapy if adverse events or treatment failure occurred, and also had a more optimal matching of patients to TDF, TAF and abacavir / dolutegravir / lamivudine (Triumeq), depending on baseline patient characteristics. The step therapy scenario initiated all patients on TDF and allowed them to switch to TAF or another treatment after the occurrence of a renal or bone adverse event or other treatment failure. For purposes of this memo, the results of the model by Baumgardner et al., 2018 were scaled to a population representing patients with HIV in care who are insured through...
Medicare (25% of the US population with HIV in care). Results are presented for a 10-year time horizon beginning in 2020 (when the proposed rule would go into effect).

II. Implications of the utilization management provision

Utilization management practices, like step therapy and prior authorization, aim to reduce drug costs by requiring patients to initiate on less expensive therapies before they can access more expensive specialty ones. It can affect timely access to treatment, reduce adherence and/or lead to avoidable adverse events. As such, the current Medicare Part D Manual notes that, for HIV treatment, “prior authorization and step therapy are generally not employed in widely used, best practice formulary models.”

Applying the model of Baumgardner et al. to the Medicare population suggests that the utilization management provision in the proposed rule could result in 7,200 additional all-cause deaths and 84,000 more renal and bone adverse events from 2020 through 2029 if patients were subjected to step therapy, compared to a policy with no access restrictions to treatment. The cost of these adverse events would be approximately $1.08 billion higher (in discounted 2020 dollars). These additional costs include all the medical care used to treat the additional bone and renal adverse events including costs of inpatient hospital, office-based provider, outpatient hospital, prescription drugs, and emergency department care. Further, this provision could lead to over 6,750 new HIV infections from increased viral loads among Medicare patients with HIV. Those 6,750 additional infections would be transmitted from the Medicare population but the new cases would be distributed across the general population meaning that those new patients who received treatment and were insured would have various sources of coverage including private payers, Medicaid, and Medicare.

III. Implications of the drug formulation and drug pricing provisions

Both of these provisions could have the impact of eliminating a drug (or possibly a number of drugs) from a formulary if it did not meet the requirements. Drug formulation is especially important for HIV therapies, as single-tablet regimens (STRs), compared with multi-tablet regimens (MTRs), have been associated with greater retention in care and treatment efficacy. Other research has shown that STRs are associated with a lower risk of hospitalization, compared with MTRs. Further, by completely restricting access to some HIV treatments through these provisions, patients who develop drug resistance may no longer have viable treatment options. Evidence also has suggested patients treated with newer ART regimens may be less susceptible to drug resistance, which further highlights the benefits of broad access to novel ARTs.

Based on the model of Baumgardner et al., restrictions that made TAF-based ART unavailable, akin to what could occur if the provisions on drug formulation and drug pricing were implemented, could lead to 8,000 additional all-cause deaths and 87,600 additional renal and bone adverse events between 2020 and 2030, compared to open access treatment. The incremental cost of these adverse events would be over $1.1 billion from 2020 through 2029. Lastly, restricting access to TAF could lead to over 7,600 new infections from 2020-2029 as a result of increased viral loads from use of suboptimal therapies among patients with HIV.

The potential effect of the three proposed Part D rule changes together are likely quite similar to the estimates in this section of the memo, that is, it would not be correct to add the numbers in sections II and III of this memo. As is evident, most of the negative consequences of the combined proposal come from the potential elimination of treatments with high efficacy and low adverse event rates from the first line of treatment, which can happen under both step therapy designs and under provisions that could eliminate a drug from the formulary. Thus,
the vast majority of the costs of the full proposal would arise from greater use of step therapy alone.

IV. Conclusion

Broad access to ART is important for patients with HIV to ensure adherence, reduce viral load, and prevent disease transmission and avoidable adverse events. In addition to the potential impacts on patients, there are a number of social and political implications of the proposed rule. Broader use of utilization management could enable Part D plans to engage in discriminatory practices by using these practices to deter patients with HIV from enrolling in their plans. Further, the drug pricing provision could lead to an increase in launch prices of drugs in the protected classes in order to avoid being removed from formularies if market conditions suggested future price increases. Lastly, the risk of additional, and preventable, HIV infections may be greater as a result of the proposed rule if patients are unable to access therapies that will maximize their adherence and reduce their viral load or if individuals at risk of HIV are unable to access PrEP. While the protected class status is important for the six categories of drugs, the preventive and treatment benefits of ART necessitate policies that promote, and do not restrict, comprehensive treatment access.

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References

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