Prior Authorization

Prior Authorization (PA) is the practice of restricting access to prescribed medications by insurers or payers based on certain criteria. This is accomplished by requiring that a prescription medication receive special approval by the insurer prior to being filled by the pharmacy. Prior Authorization properly used can help direct patients to appropriate treatments. Unfortunately, prior authorization is increasingly being used as a tool by insurers to slow or stop the use of high-cost medications, even when they are the standard of care for that condition.

Prior Authorization restrictions on HIV and HCV medications is a serious and growing issue for both HIV providers and patients.

The Problem for Patients

For patients living with HIV prior authorization requirements can mean unnecessary delays in getting the medications they need to manage their health condition. Patients often run out of medications while waiting for a prior authorization approval.

This is a particularly serious problem because even a short delay can trigger the occurrence of viral resistance. Once viral resistance occurs, the medication is rendered ineffective, and the entire class of medications may no longer be an effective treatment option. Decreased health, co-morbid conditions, and hospitalizations also result from disruptions in access to necessary medications.

The Problem for Public Health

Inappropriate use of prior authorizations also leads to significant costs to patients, providers, and the health system as a whole. Patients with HIV infection who develop viral resistance, co-morbid conditions, and hospitalizations due to disruptions in accessing medications they require create additional costs to the patient, the coverage entity, and to the health system as a whole. Outside of the limited circumstances where prior authorizations support clinical effectiveness and safety, the costs far exceed supposed benefits.

Delays in treatment prevent individuals from achieving continual viral suppression, increasing their ability to transmit HIV.

The Problem for Providers

For medical providers who write prescriptions, and pharmacists who fill them, prior authorization requirements create hours of extra office work responding to bureaucratic hurdles for individual patients that do not result in improved care.

The prior authorization appeals process differ significantly between payers and plans, creating a labyrinth of requirements, procedures and hurdles. The number of payers that providers deal with has also increased exponentially across the country with the advent of the health exchanges.
In many cases, providers have had to hire additional office staff just to respond to these prior authorization requirements of dozens or even hundreds of patients with different insurers. A 2011 survey estimated the cost of clinic staff fulfilling prior authorization requirements at approximately $85,000 per full-time equivalent (FTE) physician.** However, some prior authorizations require the prescribing physician to respond directly.

In appealing for approval of necessary medication for their patients, medical professionals are often required to appeal to clerks with no clinical background who are trained to follow scripts. It is a waste of valuable medical licensure for medical providers to negotiate with clerks over determinations of medical necessity and appropriateness.

The Cost of Prior Authorization

A 2010 estimate of the uncompensated cost per prior authorization requirement in HIV clinics was $41.60 per PA.*

Another national survey indicates that the overall estimated cost of fulfilling prior authorization to the U.S. health care system is $23 to $31 billion each year.**

Both of these estimates were published before the implementation of the Affordable Care Act, which has substantially increased the number of coverage entities, plans, and formularies that providers must contend with.

Protected Class Status

The Medicare Part D program lists six “protected classes of drugs,” which are exempt from restrictions such as prior authorization. Medicare Part D Plans are required to cover “all or substantially all” antiretroviral, and immunosuppressant medications. The statute states that:

- "Restricted access to the drugs in the class would have major or life-threatening clinical consequences for individuals with a disease or disorder treated by drugs in such class."
- "There is a significant need for … access to multiple drugs within a class due to unique chemical reactions and pharmacological effects of the drugs."
- "For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."
- "CMS expects Part D sponsors will work aggressively to eliminate any interruptions of current therapy."

Similarly, some states use carve-outs for HIV medications in order to ensure their coverage without prior authorization. The California Medicaid program (Medi-Cal) carves out selected HIV AIDS treatment drugs under the fee-for-service program.

Regulations extending protected status to HIV medications in Medicaid and private insurance plans would address the burdens imposed by prior authorization for HIV providers and consumers.

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