



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

Prior Authorization Safeguards

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BIO recognizes the financial constraints states are facing as they seek to reconcile budgetary shortfalls with a steady increase in Medicaid enrollment. At the same time, state efforts to rein in escalating costs associated with administering the Medicaid program should not be at the expense of patients currently benefiting from life-saving medicines being developed by biotechnology companies.

While many states are implementing a variety of cost containment mechanisms for their Medicaid outpatient prescription drug programs, we want to ensure that patients and providers are not over-burdened by system constraints. Physicians should be able to prescribe for their patients the most appropriate therapy for an illness in balance with states' attempts to curb prescription drug and overall health costs.

Delivery of high quality care, including access to medically necessary medicines and treatments, should continue to be a priority of state Medicaid programs, and BIO will work to support that goal.

BIO has developed the following set of safeguards for legislative modifications to state Medicaid programs. The common goal in all of these safeguards is improving patient access to care while maintaining incentives for future medical innovation.

States seeking to make changes to their Medicaid drug coverage policies should embrace and incorporate the following safeguards related to coverage of innovative medicines for Medicaid recipients:

- The state should require full publication of proposed prior authorization criteria for public comment.

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- The state should provide physicians and other prescribers, pharmacists, and patients with educational materials in lay language regarding the administration of the prior authorization program prior to program inception.
- The state should make a written determination or certification that patients will not be denied medically necessary treatments and that standards of care will not be compromised.
- Prior authorization criteria and programs should be driven by clinical information and health outcomes data, based on a comprehensive review of medical compendia, peer reviewed literature, information from the medication's originator and other sources of expert information, with an emphasis on ensuring that patients receive medically necessary and timely care.
- The decision-making process of the pharmacy and therapeutics (P&T) committee should be an open and transparent process which allows for public comment, submission of relevant information and review by health care providers and interested parties.
- Interested parties should be permitted to submit information to the State and the P&T committee for consideration when creating prior authorization criteria.
- The P&T committee should obtain input from practitioners with expertise in the class of drugs or biologics under review by the committee, and from those practitioners with expertise in the management of the diseases or conditions for which the drugs or biologics are prescribed.
- Endorsing prescribers should have the authority to indicate on the prescription form that a medication is medically necessary for a given patient and must be dispensed as written, eliminating the need for additional review or approvals. Failure to make such an indication should trigger the prior authorization process and should *not* be taken as approval to switch the medication to a preferred medication.
- Prior authorization granted to individual patients should be valid until such time that a clinical decision has been made by the prescriber that the medication is no longer needed.

- The patient and prescribing physician should be provided with a response by telephone or other telecommunication device within 2 hours of receiving a request for prior authorization. If a response to the prior authorization request is not received during this time frame, the request will be considered automatically approved. Physicians and other primary care providers should have ready access to an easily reachable clinician when a prior authorization request is being made.
- The Department should permit the dispensing of at least a 72-hour supply of the prior authorized drug in the case of an emergency as determined by the prescriber.
- Access to a representative to discuss a prior authorization request should be available 24 hours a day, 7 days a week.
- The patient and prescribing physician should be provided with an expedited independent appeals process for coverage denials.
- Continuity of care should be provided by permitting continued or standing approval for a prescription if the patient stays on the medication and remains under the care of a physician. Patients stabilized on medications at the time prior authorization goes into effect or at the time a patient joins the program should be exempt from the prior authorization process.
- Prior to implementing a prior authorization requirement on any product, the state should provide a publicly-available analysis of the potential costs associated with the use of prior authorization, including increased costs stemming from additional physician visits, diagnostic tests or hospitalizations that result from medication switches; increased physician time spent navigating the prior authorization system; and increased costs to states incurred to implement and administer the prior authorization program.
- For drugs that are subject to prior authorization, a specific set of clinical criteria should be made available to physicians and patients specifying when the drug is authorized for coverage. As with the general criteria for prior authorization, this should be open for public comment when implemented and to revision over time based upon availability of new data.