Managing Payers' Expectations Concerning Drug Safety

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Payers want many assurances from pharmaceutical companies

Before recommending coverage of a new drug for their group health benefit plans, payers (*i.e.*, insurance companies, employers, patients, payers of private and public drug plans, *etc.*) want to know that the drug has value—that it is either cheaper or better than the products already available for a particular condition and that plan members' lives and productivity will be enhanced as a result of having access to the new medication.

And now, more than ever before, payers want assurances that the product is safe. Burnt by situations in which a product was suddenly pulled from the market because of safety concerns, payers are becoming more vigilant and are starting to ask more questions before reimbursing the cost of new drugs, such as:

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- What is the body of evidence regarding the drug's safety?
- What are the potential safety concerns?
- How will drug safety be monitored once the drug is on the market?
- Under what circumstances will the drug be considered unsafe?
- How will patients be managed in the event of a safety issue, whether the drug is pulled entirely off the market or patients' treatment is monitored in a structured fashion?

Pharmaceutical companies must not only be able to convincingly answer these questions, they should also anticipate more questions and be prepared to respond. To do otherwise will only increase skepticism regarding the safety of the new drugs.

Launching a new drug

The following are proactive steps that pharmaceutical companies can take to address payers' safety concerns when launching a new drug:

1. **Educate payers**
   - Provide as much user-friendly summary information as is feasible regarding what is known about the drug's safety profile
   - Be transparent
2. **Conduct safety studies**
   - Conduct either a large one-time safety trial to validate and support existing data or ongoing sampling
   - Share the results and data with payers
   - Share your recognition with payers and the acceptance that prescription drugs are powerful agents that have the potential to provide great benefit, but also require vigilance when prescribed
3. **Introduce a patient registry**
   - While this may sound like an onerous undertaking, it may not be necessary to enroll each and every patient, but to monitor a statistically relevant sample
   - If the drug's safety were ever challenged, a registry could serve a dual purpose:
     - provide data
     - provide a framework and infrastructure to continue marketing of the product
     - help to avoid a complete withdrawal
4. **Develop a risk management plan**
   - Payers do not want to answer calls from their policy holders and plan members whenever a safety concern about a product surfaces
   - It is important to promote medical information hotlines and a plan to manage patients' concerns
5. **Communicate**
   - Notify payers of issues before they learn about them from the evening news or national newspapers
   - Build and maintain relationships with payers so that the door is opened and remains open to continuous discussion

Concluding thoughts

In this newly arrived era of hypervigilance, pharmaceutical companies will be held to greater accountability. As the line between regulation and reimbursement starts to blur, drug safety will no longer be just a regulatory matter. CPM

To discuss your payer strategy needs, please contact Rose Fishman, VP McKesson Specialty Pharmaceutical Solutions at 1 (800) 811-9880 ext. 104 or ***rfishman@phase4health.com****.*

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