Timeout!
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We were working through our usual busy agenda during our P&T committee meeting at Thomas Jefferson University when an item caught me by surprise. A member of our urology department was attempting to explain why we ought to approve a new prostate cancer drug that costs a jaw-dropping $93,000 per course of therapy. His words caused me to straighten up in my chair and to lean in closely so that I could try to understand the ramifications of what we were deciding.

As I'm sure many of our readers are aware, men with prostate cancer have two new therapeutic options with the approvals of sipuleucel-T (Provenge, Dendreon) and cabazitaxel injection (Jevtana, Sanofi-Aventis). Sipuleucel-T is an important scientific advance, as it is one of the pioneering cancer vaccines to show prolonged survival. Cabazitaxel is not a new scientific breakthrough, but it does offer an option for patients who are not a new scientific breakthrough, but it does offer an option for patients who have not responded to docetaxel (Taxotere, Sanofi-Aventis). (For more information about sipuleucel-T, please see this month’s Drug Forecast column on page 197.)

According to Lee Newcomer, MD, a leader of oncology services for UnitedHealthcare, the addition of these two drugs now makes the average total cost of care for a prostate cancer patient (at his company), from diagnosis to death, set at $672,054. This means that the two new drugs will increase the total cost of care, from UnitedHealthcare’s perspective, by 210%. For this increased expenditure, the few patients fortunate enough to respond would gain an additional 6.5 months of life.

What is really happening here, I wondered, as the discussion of sipuleucel-T continued. Then it hit me; what was going on, in fact, was the usual scenario. In our society, drug companies, now competing in an amazing biotechnology-driven industry, continue to make new discoveries, and the diffusion of new products is still largely a random process. Our committee members were simply witnessing the end-game of this process firsthand.

Although I ultimately voted to approve putting sipuleucel-T on our formulary, I realized that our good intentions could possibly go awry. We need an evidence-based approach to the selection and approval of these high-tech, high-cost products. The evidence that they will be effective is still razor-thin. Even the most jaded among us reacts to a $93,000 price tag with sticker shock!

Could we have done anything differently? As a nation, we are going to have to make some tough decisions, especially in the post–health care reform era. We must accept that not every institution can approve every new product. There simply isn’t enough money in the Medicare Trust Fund, as an example, to provide every prostate cancer patient with this new therapy. As soon as patient advocacy groups get wind of a possible special Medicare review of these products, they swung into action, flooding the Centers for Medicare and Medicaid Services (CMS) with public comments and enlisting support from senators who had survived cancer.

I am aware that sipuleucel-T is not for every patient. I also recognize that when the manufacturing shortage dissipates, overall utilization will increase.

We need to take a collective timeout here. We must ensure that the right patients are going to receive this therapy under the supervision of the right physicians, at the right time, and under the right circumstances. This might mean that individual institutions will need to create evidence-based selection criteria. It might also mean restricting the use of this vaccine to investigational subspecialists who are accustomed to working in a clinical trial–like setting. It might mean that in certain parts of the country, hospital ethics committee members will be drawn into the clinical decision-making apparatus. And yes, it might mean saying “no” on appropriate occasions.

As we have discussed in this space many times before, if we don’t take these steps collectively, we will almost certainly be headed toward a system like the National Institutes for Clinical Excellence (NICE) in Great Britain. I think that we must also acknowledge that only those patients with adequate health insurance will be eligible to receive these newer products. This restriction creates an environment of economic rationing for these kinds of advances. For now, I see no way around this conundrum.

I agree with Dr. Newcomer when he says, “using the therapy for patients who do not meet precise indications is simply conducting a $93,000 clinical trial with one subject.” This is a provocative statement, but it is, unfortunately, true.

I hope that your P&T committee will begin to assess the indications for therapy with sipuleucel-T; that it will conduct a Drug Use Evaluation (DUE) in the next few months to track adherence to the criteria you have set forth; and that it will perform an ongoing evaluation of the entire approval and tracking process for future products like sipuleucel-T. We simply must take responsibility for the diffusion of these products into everyday practice, even if it means taking a collective timeout.

As always, I’m interested in your views. You can reach me at david.nash@jefferson.edu. Please also check out my blog at http://nashhealthpolicy.blogspot.com.

REFERENCES