Appendix 5.6.1
Blue Cross Blue Shield Technology Evaluation Center (TEC) Assessment

For many private health plans, including Blue Cross Blue Shield (BCBS), FDA approval is not sufficient to establish reimbursement coverage. Before making a coverage decision, the plan will review data supporting the intervention and assess its benefits relative to comparable therapies, as well as its overall effect on health outcomes. While not all health plans conduct internal technology assessments, many follow the recommendations published by entities such as BCBS TEC. BCBS and other plans are concerned that the limitations of clinical trials, used solely to gain FDA approval, fail to give the physician enough information to fully assess the strength of the new technology. Health plans under political pressure have been observed to cover technologies that have not been fully evaluated, only to find after a period of time that the interventions are definitively not helpful or even may cause harm.[1]

Tysabri, a therapy for multiple sclerosis co-marketed by Biogen Idec and Élan, provides one such example. This product was launched in the U.S. after accelerated FDA review in the fall of 2005. Many payers were asked to cover it before complete data from phase III clinical trials became available so that patients would not be denied access. However, in February of 2005, Tysabri was pulled from the market after causing death and severe disability in a handful of patients.[2]

Generally, interventions will be chosen for TEC evaluation if they have the potential to cause serious side effects, are indicated for a large treatment population, and/or the cost of the technology is high. The TEC committees make their final recommendations based on the following criteria:[3]

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Conclusions are generally drawn on the basis of relevant evidence from clinical trials and analysis of cost models, with only limited influence from expert opinion or current prevailing community medical practice. While BCBS allows comments and materials to be submitted and considered by BCBS officials involved in the decision, the final decision-making process is closed, and generally includes only internal or invited experts to testify. This is in contrast to the assessment process at the FDA, CMS, and certain other health plans. For this reason, it is important to reach BCBS early with materials and contacts to ensure that officials go into this meeting with enough information to rule favorably on the technology.

[1] David M. Eddy, "Technology Assessment, Deployment, and Implementation in Prepaid Group Practice," *Toward a 21st Century Health System: The Contributions and Promise of Prepaid Group Practice* (Josey-Bass: San Francisco, 2004) pp. 85-107.
[2] "Natalizumab," Wikipedia.org, http://en.wikipedia.org/wiki/Natalizumab (March 21, 2014).
[3] "Technology Evaluation Center Criteria," Blue Cross Blue Shield, http://www.bcbs.com/blueresources/tec/ (March 17, 2014).

