State and Public School Life and Health Insurance Board Clinical and Fiscal Drug Utilization and Evaluation Committee Minutes
May 28, 2008

The State and Public Life and Health Insurance Board, Joint Clinical and Fiscal Drug Utilization and Evaluation Committee met on Wednesday, May 28, 2008 at 8:30 a.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Members Present:
Dr. William Golden
Mark McGrew
Kat Neill
Larry Dickerson
Dr. Joe Stallings
Robert Watson

Members Absent:
Dr. James Bethea
Dr. Hank Simmons
Matthew Hadley

Sharon Dickerson, Executive Director, Employee Benefits Division of DFA

Others Present:
Shelby McCook, Janis Harrison, Renee Mallory, Bobbie Davis; Board Members; Barry Fielder, NMHC; Jill Johnson, Dr. Mark Helm, College of Pharmacy, UAMS; Jason Lee, Amy Tustison, Marty Usrey, Kim Wilmot, Shannon Roberts, Sherry Bryant, Kristi Cox, Faith Houston, Cathy Harris, EBD; Bryan Meldrum, Novasys; Ronda Walthall, Wayne Whitley, AHTD; Jeff Britt, Pfizer;

Call to Order
Meeting was called to order by Dr. Golden.

Approval of Minutes
The request was made by Dr. Golden to approve the May 5, 2008 minutes. Minutes were approved without objection.

REVLIMID (LENALIDOMIDE) ***by Mark E. Helm, MD***
An Emergency meeting was called on May 28, 2008. Some of the Board members were present for the discussion.

Helm informed the committee that one of the plan's Oncologists would like for the drug Revlimid to be preauthorized for a patient with chronic lymphocytic leukemia (CLL). Helm said the Oncologist believes that the proposed treatment would be better tolerated and the treatment would have some effect in slowing the patient's progression.

Helm explained the use requested is not among those for which Revlimid can be covered by the plan because it is an experimental use.

Helm talked about the additional options provided by Celgene's medical affairs for clinical trials of Revlimid in CLL. Celgene's recommendation is that Revlimid use for CLL should only occur in the context of a clinical trial.

Helm said the Oncologist has since referred to the Arkansas version of a Federal law that specifically addresses the use of FDA approved drugs for cancer when they are used for a cancer indication other than the one stipulated on the label.

Helm explained in situations such as this where there is only a limited evidence-base from which to draw, it is sometimes not possible to make a recommendation for or against a potential medication usage.

Dickerson explained that they are a self-insured government plan and ERISA exempt and the plan's Summary Plan Description (SPD) outlines that they do not cover investigational or experimental drugs.

Dr. Golden said there is very little published about the drug and CLL; then referenced to material from PubMed. Dr. Golden said there is enough evidence that the drug should be used in clinical trials; which means that there is enough evidence for it to be used in the experimental environment.

McGrew and Dickerson discussed which benefit plan is responsible for the drug; the medical side or the pharmacy side. McGrew said from what little information he has received; the drug is obtain in specific ways that are a little outside the ordinary routine and there are some questions about availability also.

Dickerson explained that the benefit would be provided by the pharmacy program.

Fielder explained there is limited distribution for the drug and only 3 or 4 special pharmacies that have access. McGrew clarified that the specialty pharmacies would have to be in the program in order for them to obtain the drug.

Dr. Golden commented cancer therapies are very expensive and some of the treatments are not "standard". Should the plan support unfunded (or funded) clinical research? What is appropriate coverage?

A discussion ensured for the following:

- Is this drug for this condition experimental?
- Should it be considered as alternative therapy if the patient is going to get a bone marrow transplant?
- How aggressive or how far is an individual patient entitled to get therapy?
- Would the Board cover it if the alternative therapy would be potentially more expensive or preferred by the plan?

Mary Usrey, EBD Health Services Case Manager informed the Board that she previously worked for a myeloma clinic as a clinical nurse case manager. Usrey stated that they can not actually say that Revlimid can forestall a bone marrow transplant. Usrey informed the committee that the nearest clinical trial is in Shreveport and suggested that they direct the patient there so the drug can be provided. Usrey said response data can be captured and that can be beneficial to some of the other members done the road.

Neill said the drug is still considered experimental and that's sort of a flag that there is probably not a lot of compelling information available that support the use of the drug in this disease process. Neill said obtaining unique information from ongoing experimental trials for this and other particular disease processes can help them make their decisions going forward.

Motion: Neil made the motion; given the data that is available, Revlimid is still considered an experimental drug and to view it as an experimental drug for CLL. As new information becomes available, the DUEC will reconsider the issue at any appropriate time. EBD will communicate with the physician about the committee's decisions.

Dr. Golden concluded that the broader problem will need to be examined by EBD and ultimately the board to avoid case by case angst.

Meeting Adjourned.