P&T Committee
Teleconference Minutes

Date: April 29, 2005

Chair: Michael Flaum, M.D.

Time: 12:07 p.m. to 12:20 p.m.

Location: Telephonic. Public location is Iowa Foundation for Medical Care Executive Board Room.

Committee Members Present via telephone: Cheryl Clarke, R.Ph., CDM; Michael A. Flaum, M.D.; Carole A. Frier, D.O.; Hayley L. Harvey, DDS, MS; Susan Purcell, R.Ph, CGP; and Priscilla Ruhe, M.D.

Committee Members Absent: Bradley J. Archer, MD; William R. Doucette, Ph.D.; and Mary Winegardner, PA-C, MPAS

Iowa DHS Staff Present via telephone: Eileen Creager, Bureau Chief; and Brad Horn, Attorney General's Office

Iowa DHS Staff Present in Executive Board Room: Susan Parker, Pharm.D., DHS Pharmacy Consultant

IME Staff Present via telephone: Tim Clifford, M.D.; John Grotton, R.Ph.; Thomas Kline, D.O., Iowa Medicaid Medical Director; and Andi Dykstra, R.N., CPHQ

IME Staff Present in Executive Board Room: Sandy Pranger, R.Ph.; Julie Bueno, R.Ph., and Liz Levings, Administrative Coordinator

1. Sandy Pranger welcomed everyone. She explained the purpose for the teleconference was to go over the new drug process and that this could not wait until the next scheduled meeting.

2. A role call was taken.

3. Dr. Clifford reviewed the current new drug process review. Dr. Clifford stated that all new drug entities (including new generics), and new drug product dosage forms of existing drug entities in therapeutic classes of drugs already reviewed by the P&T Committee, will be identified weekly from the DHS First Data Bank price update reports, and then immediately be coded as "Non-preferred-Prior Authorization required." These drugs will be considered non-preferred until presented at the nearest quarterly scheduled P&T Committee meeting. These prior authorization restrictions will continue through the review process, including while committee recommendations are being made, and lasting

until DHS makes a final determination. New drug entities in therapeutic classes not yet reviewed by the P&T Committee will remain payable, in effect preferred by default, until the therapeutic class is discussed. Once this review occurs for the class, the non-preferred default policy will apply to subsequent new drug entries. There are two major potential exceptions to the non-preferred default policy for new PDL drugs. First, if a new medication is considered unique, and has been classified as a priority drug by the FDA, the State may indicate that such a drug is preferred, until the drug is reviewed by the P&T Committee at the nearest scheduled meeting. Second, the State may decide to designate a new drug as "draft preferred" on the basis of net cost, with or without a supplemental rebate, and provide immediate access and increased therapeutic choice to physicians, until the drug is reviewed by the P&T Committee at the nearest scheduled meeting. Although the State discourages supplemental rebate offers on existing PDL drugs between annual bidding periods, it may entertain such bids and may accept them if they are determined to represent significant, additional savings, or if they would replace a delinquent manufacturer's product or a preferred drug pulled from the marketplace or significantly restricted by the FDA. This interim preferred status will remain in effect until the drug is reviewed by the P&T Committee at the nearest scheduled meeting. Supplemental rebates will only be invoiced for approved drugs under contract. Draft preferred drugs with supplemental rebates, will not be invoiced until approved by the Committee and accepted by the State. At that time, the supplemental rebates will be invoiced back to the effective date of the agreement, at which time the drug began to benefit from preferred status.

4. Dr. Flaum summarized what Dr. Clifford had reviewed, clarifying that new drugs could be draft preferred until the next meeting. Dr. Flaum asked Dr. Clifford if that was the main issue. Dr. Clifford responded that it was the main issue from the positive direction in terms of being able to accept supplemental rebates over the interim potentially. The other side of it is being aware of the operating default policy which is ordinarily all new drugs coming out would be considered non-preferred until the next P&T Committee meeting. Dr. Flaum clarified that it was the default policy, but wanted to know if Dr. Clifford was asking for clear Committee approval that there could be exceptions to the default policy. Dr. Clifford responded that yes, they were trying to give greater clarity to try to identify those potential exceptions. Dr. Ruhe asked who made that decision about draft preferred. Dr. Clifford responded that the draft preferred decision is a recommendation by IME. Dr. Ruhe asked if this is the way the State of Maine operates, to which Dr. Clifford responded yes. John Grotton reminded the Committee to keep in mind that no rebates would be billed or collected if the Committee chose not to approve that status. Dr. Flaum asked John Grotton if this would allow for negotiations. John Grotton replied yes. Dr. Clifford added that this would also allow physicians to access new drugs during that interim period even though the State would be assuming a certain amount of risk with allowing that early access. Sue Purcell expressed concern of patients being started on a new medication and then being taken off of it. She also asked what the allowances for that would be and what kind of notification information would the pharmacists, physicians, and patients have of any changes. Dr. Clifford said that was a theoretical risk and one that he would feel a lot better about once we have charge of the claims processing system so that we can accommodate that, but on the other hand he

thinks that there was pretty good agreement between the Committee's decision and IME's recommendations on how to treat most of the drugs on the PDL. Even though there is a potential liability, Dr. Clifford feels there would be possible benefits to physicians having this type of access, and also that there is a lot of value to potentially getting on board with some of the products as they become available. Dr. Flaum asked if the billing would be taken over by GHS on July 1st to which Dr. Clifford responded yes. Dr. Ruhe inquired if there would be a sense of logic and cooperation at that time about a person who is having an issue and Dr. Clifford agreed. Dr. Ruhe agreed then as this will be a two-month period and therefore would be a minimal problem.

5. Dr. Flaum asked Dr. Clifford if he was asking the Committee for approval of formal language. Dr. Clifford deferred the question to Susan Parker, who asked Brad Horn whether a role call vote should be taken and have a formal recommendation from the Committee. Brad Horn said that the Committee needed to vote on this.

6. Dr. Flaum made a motion that the policy as read by Dr. Clifford be approved. Dr. Ruhe seconded the motion.

7. Cheryl Clarke asked if the Committee would be getting a copy of this so that there would be a good indication of what was approved. Dr. Flaum asked Cheryl Clarke if she would rather hold off on voting to which Cheryl Clarke replied that she does not feel strongly about it and would rather have a copy of it. Susan Parker told Cheryl Clarke that this is on the June agenda. Dr. Ruhe asked if this is part of the public minutes of the Committee, to which Sandy Pranger replied that minutes would be sent to the Committee members and it was on the June agenda. Cheryl Clarke said this was fine with her.

8. A role call vote was taken:

    - Cheryl Clarke = Yes
    - Dr. Flaum = Yes
    - Dr. Frier = Yes
    - Dr. Harvey = Yes
    - Susan Purcell = Yes
    - Dr. Ruhe = Yes

As there was no other business for the Committee, the teleconference concluded at 12:20 p.m.