STATE OF IOWA

THOMAS J. VILSACK, GOVERNOR
SALLY J. PEDERSON, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
KEVIN W. CONCANNON, DIRECTOR

Iowa Medicaid Pharmaceutical and Therapeutics (P & T) Committee Meeting
June 8, 2006

Location: Grimes Building
400 East 14th Street
State Board Room, 2nd Floor
Des Moines, Iowa 50319

Time: 9:30 a.m. - 4:30 p.m.

Tentative Agenda

1. Welcome & Introductions
    a) Committee Members and Staff
2. Approval of the minutes
3. Update
    a) Legislation
    b) Preferred Drug List (PDL)
    c) Prior Authorization Criteria **(See attachment 1)**
    d) Drugs of Smoking Cessation and Weight Loss **(See attachment 1)**
    e) Policy for review of drug status on the PDL (action item **See attachment 2**)
4. Public Comment **(See attachment 3 for Conflict of Interest Disclosure)**
5. Closed Executive Session
    a) Economic Review of the Iowa Medicaid Preferred Drug List, Newly Released Drugs, Newly Released Generic Drugs, New Dosage Forms, and Contracts.
    b) Review and discussion of the confidential public comments.
6. Preferred Drug List (PDL) discussion and deliberation

    (See attachment 4 for order of discussion)
7. Final Recommendations by the P & T Committee on the Iowa Medicaid Preferred Drug List

    Lunch Break 12:15 p.m.-1:00 p.m.
8. Review of Newly Released Drugs by Dr. Thomas Kline

    (See attachment 5 for order of discussion)
9. Final Recommendations by the P & T Committee on Newly Released Drugs (Open Session)
10. Review of Newly Released Generics drugs and New Dosage Forms and Strengths by Dr. Tim Clifford

    (See attachment 6 for order of discussion)
11. Final Recommendations by the P & T Committee on Newly Released Generic Drugs and New Dosage Forms and Strengths (Open Session)

Disclaimer: Executive Sessions may be necessary during the deliberation process

www.IowaMedicaidPDL.com

For more information contact Sandy Pranger at spranger@ghsinc.com or (515) 725-1272

Attachment 1

Per request of the Department of Human Services, the DUR Commission discussed the prior authorization criteria for three categories of medications at its May 3, 2006 meeting. These categories were polyethylene glycol 3350, weight loss medications, and smoking cessation medications. **The following are the recommendations of the DUR Commission.**

Single ingredient PEG products	Prior authorization is required for single ingredient polyethylene glycol 3350 products. Payment for single ingredient polyethylene glycol 3350 products will be authorized only for cases in which there is documentation of previous trial(s) and failure with a preferred senna product used for constipation.

Smoking cessation agents: nicotine replacement therapy	Prior authorization is required for over-the-counter nicotine replacement patches. Requests for authorization must include diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling. Confirmation of enrollment in the Quitline Iowa counseling program is required for approval. Initial approvals will be granted for 4 weeks at one unit per day with two additional approvals available with documentation of therapy success from Quitline Iowa. Maximum allowed duration of therapy is 12 weeks per 12-month period. Approvals will only be granted for members who are 18 years of age or older.

Pending implementation of the weight loss disease management program, the DUR Commission recommends no change in the medications covered for weight loss and no change in the current PA criteria for this category. Based on a review of current medical literature, the Commission expressed concerns regarding the safety and efficacy of these medications. The demonstrated efficacy is relatively minimal when balanced against the potential adverse effects of these medications. Most importantly, the Commission believes that pharmacotherapy for weight loss is indicated only as part of a comprehensive weight loss program. In order to effectively provide the Department with guidance on how to best utilize medications as an adjunct to a comprehensive weight lost program, the Commission would need further knowledge of the operations and funding sources of such a program that would provide such access to patients. The Commission respectfully requests the opportunity to continue its review of this category as the Department designs its weight loss disease management program. The Commission believes there is a subset of patients who may benefit from these medications. The Commission concludes that integrating the appropriate use of these medications into the operations of a comprehensive weight loss program is the best strategy to ensure cost-effective use of this category of medications.

Attachment 2

Preferred Drug List (PDL)/Recommended Drug List (RDL)

Policy for Review of Drug Status on the PDL/RDL

A. All drugs on the PDL/RDL are reviewed at the annual Pharmaceutical and Therapeutics (P & T) Committee Meeting held in the last quarter of the calendar year.

B. Newly introduced products to the market, with or without submitted supplemental rebate offers, are reviewed by the P & T Committee at the next scheduled quarterly P & T Committee meeting.

C. Recently introduced drugs that were initially reviewed without a supplemental rebate consideration (see B above), may upon the receipt of a valid supplemental rebate offer be reviewed at the discretion of the P & T Committee at the next quarterly P & T Committee meeting.

D. All P & T Committee Meetings include an opportunity for Public Comment. All public members, including drug manufacturers, have the opportunity to speak before the P & T Committee about any product. Additionally, Public Comments may be submitted via the website, www.iowamedicaidpdl.com, at all times. These comments are posted to the website and all hardcopies are presented to the P & T Committee at each meeting. It is at the discretion of the P & T Committee to re-discuss drugs mentioned during Public Comment.

E. Drugs may not be eligible for review if existing contract(s) with other labeler's products precludes additional preferred products within the same therapeutic class on the PDL.

F. Minutes of the P&T Committee meeting will include the basis on which a drug status recommendation on the PDL/RDL was made.

G. Manufacturers requesting reconsideration of the status of a product on the PDL/RDL will only be considered if there is new supporting information (i.e. new clinical information or cost data) that impacts the original decision made by the P&T Committee. The request must be submitted by e-mail within five business days following the date of the P & T Committee meeting at which the recommendation was made. The request must be e-mailed to info@iowamedicaidpdl.com.

Attachment 3

State of Iowa
Conflict of Interest Disclosure

The Iowa Medicaid Pharmaceutical and Therapeutics (P&T) Committee and persons testifying or presenting to the Iowa Medicaid P&T Committee are asked to disclose any financial or other affiliation with organizations that may have a direct or indirect interest in the business in front of the Committee.

A financial interest may include, but is not limited to, being a shareholder in the organization; being on retainer with the organization; or having research or honoraria paid by the organization.

An affiliation may include holding a position on an advisory committee or some other role or benefit to a supporting organization.

The existence of such relationships does not necessarily constitute a conflict of interest and will not preclude an individual from participating on, or addressing the P&T Committee. This policy is intended to openly identify any potential conflicts so that the P&T Committee members and the public are able to form their own judgments.

Please check the box of the statement that best applies.

- ❑ **Statement of No Conflicts**
  I do not have a current or recent (within the last 12 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the Iowa Medicaid P&T Committee.

- ❑ **Disclosures**
  I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the Iowa Medicaid P&T Committee

- ☐ **I refuse to state my affiliations**

Organization	Role/Relationship

_____

(print name)

_____

(signature) *(date)*

Attachment 4

Iowa Medicaid Preferred Drug List

Disclaimer: The Iowa P & T Committee reserves the right to re-evaluate all medications within the same therapeutic category as those on the agenda scheduled to be discussed for the PDL Review, New Drug Review, New Generic Drug Review, and New Dosage Forms Review and vote to change the PDL status of other medications currently on the PDL. It is the responsibility of the drug manufacturer to provide representation, if necessary, at the P & T Committee Meeting when a competitor's product is on the agenda for discussion.

1. Feiba VH – Recommend status on RDL as non-recommended; drug has not previously been discussed by P & T Committee
2. Maxair Autohaler - Recommend change in PDL status to preferred
3. Mebendazole – Recommend change in PDL status to preferred
4. Polyethylene Glycol (PEG) – Recommend change in PDL status to non-preferred with PA Criteria

Attachment 5

Newly Released Drugs

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1. Amitiza – Recommend status on PDL as non-preferred
2. Mimyx Cream – Recommend status on PDL as non-preferred
3. NeoBenz Micro – Recommend status on PDL as non-preferred
4. OptiNate – Recommend status on PDL as non-preferred
5. Ranexa – Recommend status on PDL as non-preferred
6. Sutent – Recommend status on RDL as recommended
7. Taclonex – Recommend status on PDL as non-preferred
8. U-Kera – Recommend status on PDL as non-preferred
9. Vivaglobin – Recommend status on PDL as non-preferred
10. Vusion Ointment – Recommend status on PDL as non-preferred

Attachment 6

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NEWLY RELEASED GENERIC DRUGS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Cefprozil	Cefzil/Preferred	Non-Preferred
Fluticasone Nasal Spray	Flonase Nasal Spray/Preferred	Non-Preferred

NEW DOSAGE FORMS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Atrovent HFA	Atrovent/Preferred	Preferred
Boniva Injection	Boniva/Non-Preferred	Non-Preferred
Climara Pro	Climara/Non-Preferred	Non-Preferred
Loestrin 24 Fe	Loestrin Fe/Non-Preferred	Non-Preferred
RibaPak	Rebetol/Preferred	Non-Preferred
Zegerid Capsules	Zegerid/Non-Preferred	Non-Preferred