STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
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DEPARTMENT OF HUMAN SERVICES
KEVIN W. CONCANNON, DIRECTOR

Iowa Medicaid Pharmaceutical and Therapeutics (P & T) Committee Meeting
March 8, 2007

Location: Department for the Blind
524 4th Street
Des Moines, Iowa 50309-2306

Time: 9:30 a.m. – 4:30 p.m.

Final Agenda

1. Welcome & Introductions
    a) Committee Members and Staff
    b) Approval of the minutes
2. Update
    a) Legislation
    b) Preferred Drug List (PDL) **(See attachment 1)**
    c) Prior Authorization Criteria/Pro-DUR edits **(See attachment 2)**
    d) New Drug Review Process **(See attachment 3)**
3. Public Comment **(See attachment 4 for Conflict of Interest Disclosure)**
4. 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

Lunch Break 12:30 a.m.-1:15 p.m.

5. Preferred Drug List (PDL) discussion and deliberation

    (See attachment 5 for order of discussion)
6. Final Recommendations by the P & T Committee on the Iowa Medicaid Preferred Drug List
7. Review of Newly Released Drugs by Dr. Thomas Kline

    (See attachment 6 for order of discussion)
8. Final Recommendations by the P & T Committee on Newly Released Drugs (Open Session)
9. Review of Newly Released Generics drugs and New Dosage Forms and Strengths by Dr. Tim Clifford

    (See attachment 7 for order of discussion)
10. 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

Iowa Medicaid Generic Utilization Rate

Issue: There is a variance in the Iowa Medicaid generic utilization rate when comparing data between the IME Data Warehouse and GHS POS System.

The Table below provides a comparison between the data used and explains why there is a difference at this point in time.

IME Data Warehouse (DUR)	**GHS POS System (P&T)**
53.77% for 9/1/05-8/31/06	60.76% for 7/1/06-9/30/06
*It is important to note that this is the average generic utilization over the specific time period represented.	*It is important to remember that this more accurately reflects "current" generic utilization, because it is the most recent quarter of utilization.
Data source is IME Data Warehouse-reference source is First DataBank.	Data source is GHS POS system-reference source is MediSpan.
Timeframe includes a years worth of data.	Timeframe includes most current quarter of data.
Timeframe includes 2005 or dual eligible, non-covered drug data.	Timeframe excludes 2005 or dual eligible, non-covered drug data.

Summary: The most accurate reflection of **"current"** Generic Utilization would be to use the most recent quarter of data from the GHS POS system until the 2005 data is no longer included and the IME Data Warehouse converts to using MediSpan. Once this occurs, the variation in comparing a year's worth of data (IME Data Warehouse) versus a recent quarter of data (GHS POS System) should be minimal.

Attachment 2

Revised Prior Authorization Criteria

Incretin Mimetic (Byetta®) *Use Incretin Mimetic form*	Prior authorization is required for incretin mimetics (Byetta®). Payment will be approved under the following conditions: 1) Diagnosis of Type 2 diabetes mellitus, 2) Concurrent therapy with metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and thiazolidinedione.

Proton Pump Inhibitors *Use Proton Pump Inhibitor PA form*	Prior authorization is not required for the preferred proton pump inhibitors (PPI) for a cumulative 60-days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trial and therapy failure with the preferred agent. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization. Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of: 1. Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas). 2. Barrett's esophagus. 3. Erosive esophagitis 4. Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses. 5. Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of Helicobacter pylori treatment or a negative Helicobacter pylori test result. Prior authorization is NOT required for Prevacid granules for oral suspension or SoluTabs for children age 12 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid granules for oral suspension and SoluTabs for patients over 12 years of age beginning day one of therapy. Authorization for Prevacid granules for oral suspension and SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form.

Short Acting Oral Fentanyl Products *Use Short Acting Oral Fentanyl Products PA form*	Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients. These products carry a **Black Box Warning**. Actiq® & Fentora®: • Are indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. • Are contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, do not use in opioid non-tolerant patients.

Attachment 3

Item #2 on the Iowa Medicaid PDL New Drug Process

Current Policy

Therapeutic classes of drugs not yet reviewed by the Pharmaceutical and Therapeutics (P&T) Committee - *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*

Proposed Policy

Therapeutic classes of drugs not yet reviewed by the Pharmaceutical and Therapeutics (P&T) Committee - *New drug entities for conditions without any available PDL choices 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 new therapeutic class, the non- preferred default policy will apply to subsequent new drug entries.*

Attachment 4

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 5

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. Adderall 5mg, 7.5mg,10mg, 12.5mg, 15mg, 20mg and 30mg tablets recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

2. Amoxil 875mg Tablets recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

3. Amoxicillin 875mg Tablets recommend to change the PDL status to preferred because it is more cost effective for the State

4. Amoxicillin/Clavulanate 400mg Chewable Tablets recommend to change the PDL status to preferred because it is more cost effective for the State

5. Amoxicillin/Clavulanate ES 600mg Suspension recommend to change the PDL status to preferred because it is more cost effective for the State

6. Amphetamine Salts 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg Tablets recommend to change the PDL status to preferred because it is more cost effective for the State

7. Atrovent 0.06% Nasal Spray recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

8. Augmentin 400mg Chewable Tablets recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

9. Augmentin ES 600mg Suspension recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

10. Azulfidine 500mg recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

11. Bupropion ER 100mg Tablets recommend to change the PDL status to preferred because it is more cost effective for the State

12. Bupropion SR 150mg & 200mg Tablets recommend to change the PDL status to preferred because it is cost effective for the State

13. Cardec Syrup recommend removing from the PDL since this product is no longer manufactured

14. Cefzil 250mg & 500mg Tablets recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

15. Cesamet recommend change in PDL category to Antiemetic – Tetrahydrocannabinol (THC) Derrivatives; no change in PDL status recommended

16. Cleocin-T 1% Gel recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

17. Clindamycin 1% Gel recommend to change the PDL status to preferred because it is more cost effective for the State

18. Clotrimazole/Betamethasone Lotion recommend to change the PDL status to preferred because it is more cost effective for the State

19. Coumadin recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State; recommend established users be grandfathered

20. Dextrostat 10mg Tablet recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

21. Diflucan 100mg, 150mg, 200mg Tablet and 40mg/mL Liquid recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

22. Ditropan XL recommend to change status to preferred for children twelve years of age and younger. This will be an age edit on the POS system.

23. Fosinopril recommend to change the PDL status to preferred because it is more cost effective for the State

24. Halobetasol 0.05% Ointment recommend to change the PDL status to preferred because it is more cost effective for the State

25. Hepsera recommend to change the PDL status to non-preferred because of the addition of new drug in this PDL category

26. Ipratropium 0.06% Nasal Spray recommend to change the PDL status to preferred because it is more cost effective for the State

27. Lantus and Lantus Opticlick recommend discussion with updated data analysis from Dr. Clifford

28. Levemir and Levemir Flexpen recommend discussion with updated data analysis from Dr. Clifford

29. Levonorgestrel and ethinyl estradiol tab 0.10mg-20mcg recommend to change status to preferred because the brand name products have been unavailable for greater than six months

30. Lithium Carbonate CR 300mg Caps recommend to change the PDL status to preferred because it is cost effective for the State

31. Lotrisone Lotion recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

32. Marinol recommend change in PDL category to Antiemetic – Tetrahydrocannabinol (THC) Derrivatives; no change in PDL status recommended

33. Monopril recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

34. Ofloxacin 0.3% Eye Drops recommend to change the PDL status to preferred because it is cost effective for the State

35. Paxil 10mg & 20mg recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

36. Paroxetine 10mg & 20mg recommend to change the PDL status to preferred because it is more cost effective for the State

37. Permethrin 5% Cream recommend to change the PDL status to preferred because it is cost effective for the State

38. Prozac 20mg/5mL Solution recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

39. Quinine sulfate products will be removed from the PDL in response to the FDA's order to remove these products from the market (F06-195 December 11, 2006)

40. Selsun 2.5% Shampoo recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

41. Ultravate 0.05% Ointment recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

42. Urised recommend to change the PDL status to preferred because the generics are unavailable

43. Wellbutrin 75mg Tablet recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

44. Xylocaine 2% Viscous Solution recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

45. Zithromax 250mg & 500mg Tablet recommend to change the PDL status to non-preferred because the generic is now more cost effective for the State

Attachment 6

Newly Released Drugs

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. Duetact- Recommend status on the PDL as non-preferred
2. Femcon Fe- Recommend status on the PDL as non-preferred
3. Fentora- Recommend status on the PDL as non-preferred
4. Invega- Recommend status on the RDL as non-recommended
5. Januvia- Recommend status on the PDL as non-preferred
6. Moviprep- Recommend status on the PDL as non-preferred
7. Noxafil- Recommend status on the PDL as non-preferred
8. Qualaquin- Recommend status on the PDL as non-preferred
9. Tyzeka- Recommend status on the PDL as preferred
10. Verdeso Foam- Recommend status on the PDL as non-preferred
11. Xolegel 2% Gel- Recommend status on the PDL as non-preferred
12. Ziana Gel- Recommend status on the PDL as non-preferred
13. Zolinza- Recommend status on the PDL as non-recommended

Attachment 7

Newly Released Generic Drugs and New Dosage Forms

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NEWLY RELEASED GENERIC DRUGS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Colestipol	Colestid/Preferred	Non-Preferred
NEW DOSAGE FORMS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Abilify Dismelt	Abilify/Non-Recommended	Non-Recommended
Travatan Z	Travatan/Preferred	Preferred