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
September 14, 2006

Location: Hoover Building
Hoover Level A Training Room 6
1305 East Walnut
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/Pro-DUR edits **(See attachment 1)**
4. Public Comment **(See attachment 2 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 3 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 4 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 5 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

<table>
<tr><td>Amylino Mimetic (Symlin®)

Use Amylino Mimetic (Symlin®) form</td><td>Prior authorization is required for amylino mimetics (Symlin®). Payment will be approved under the following conditions, 1) Diagnosis of Type 1 or Type 2 diabetes mellitus, 2) Concurrent use of mealtime insulin therapy, 3) Documented inadequate glycemic control with mealtime insulin therapy.</td></tr>
<tr><td>Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents

Use Antiemetic-5HT3 Receptor Antagonists/ Substance P Neurokinin Agents form</td><td>Prior authorizations required for preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications for quantities exceeding the following dosage limits per month. Payment for anti-emetics beyond this limit will be approved on a case-by-case basis.

Prior authorization will be required for all non-preferred Antiemetic-5HT3 Receptor Antagonists/Substance P Neurokinin medications beginning the first day of therapy. Payment for non-preferred medications will be authorized only for cases in which there is documentation of previous trial(s) and therapy failure with a preferred agent in this class. Note: Aprepitant (Emend®) will only be payable when used in combination with other antiemetic agents (5-HT3 medication and dexamethasone) for patients receiving highly emetogenic cancer chemotherapy.

<table>
<tr><td>Aloxi (N)</td><td>4 vials (0.25mg/5mL)</td><td>Zofran (P)</td><td>12 – 4mg tablets</td></tr>
<tr><td>Anzemet (N)</td><td>5 – 50mg/100mg tablets</td><td></td><td>12 – 8mg tablets</td></tr>
<tr><td></td><td>4 vials (100mg/5mL)</td><td></td><td>4 – 24mg tablets</td></tr>
<tr><td></td><td>8 ampules (12.5mg/0.625mL)</td><td></td><td>50mL/month – oral solution (4mg/5mL)</td></tr>
<tr><td>Emend (P)</td><td>4 – 125mg capsules</td><td></td><td>4 – 20mL vials (2mg/mL)</td></tr>
<tr><td></td><td>8 – 80mg capsules</td><td></td><td>8 – 2mL vials (2mg/mL)</td></tr>
<tr><td>Kytril (N)</td><td>8 – 1mg tablets</td><td>Zofran ODT (P)</td><td>12 – 4mg tablets</td></tr>
<tr><td></td><td>30mL – oral solution (1mg/5mL)</td><td></td><td>12 – 8mg tablets</td></tr>
<tr><td></td><td>8 vials (1mg/mL)</td><td></td><td></td></tr>
<tr><td></td><td>2 vials (4mg/mL)</td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Incretin Mimetic (Byetta®)

Use Incretin Mimetic form</td><td>Prior authorization is required for incretin mimetics (Byetta®). Payment will be approved under the following conditions, 1) Diagnosis of Type 2 diabetes mellitus, 2) Documented inadequate glycemic control with or contraindication to metformin, sulfonylurea, and metformin/sulfonylurea combination therapy, 3) Concurrent therapy with metformin and/or sulfonylurea unless contraindicated.</td></tr>
<tr><td>Oxycodone CR/ER (Oxycontin®)

Use Oxycodone CR/ER form</td><td>Oxycodone ER should be dosed every 12 hours. Prior authorization is required for Oxycodone ER for:
1. doses exceeding two tablets per day of the same strength or
2. for more than two strengths per month.

Prior authorization for Oxycodone ER at any dose twice daily for cancer pain will be approved. In order to receive approval for quantities or strengths of Oxycodone ER that require prior authorization, the prescriber must provide information to document the need for the medication at the prescribed dosage or quantity.</td></tr>
</table>

Attachment 2

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 3

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. Azithromycin 250mg, 500mg and 600mg tablets the PDL status was changed to preferred because more cost effective for the State

2. Campral the P & T Committee requested current safety and efficacy literature to review before discussion of PDL status change

3. Drysol to change the PDL status to preferred because the generic went OTC

4. Lithium Carbonate 450mg CR tablet to change the PDL status to preferred because the brand name product was discontinued

5. Mimyx will be removed from the PDL because CMS considers it to be a non-drug item

6. Spiriva update and DUR recommendation

7. Vivaglobin the status on the PDL is non-preferred instead of preferred with conditions

8. Zithromax Tripak to changed to non-preferred on the PDL because the Azithromycin 250mg, 500mg and 600mg became preferred

Attachment 4

Newly Released Drugs

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1. Apidra Injection and Opticlick Injection– Recommend status on the PDL as non-preferred
2. Citracal Prenatal + DHA– Recommend status on the PDL as non-preferred
3. Daytrana- Recommend status on the PDL as non-preferred
4. Durabac Forte– Recommend status on the PDL as non-preferred
5. Emsam Patch– Recommend status on the RDL as non-recommended
6. Enjuvia– Recommend status on the PDL as non-preferred
7. Opana- Recommend status on the PDL as non-preferred
8. Opana ER- Recommend status on the PDL as non-preferred
9. Optase- Recommend status on the PDL as non-preferred
10. Oracea- Recommend status on the PDL as non-preferred
11. OsmoPrep- Recommend status on the PDL as non-preferred
12. Precare Premier- Recommend status on the PDL as non-preferred
13. Prezista- Recommend status on the RDL as recommended
14. Solodyn ER- Recommend status on the PDL as non-preferred
15. Sprycel- Recommend status on the RDL as non-recommended
16. Vivitrol Injection- Recommend status on the PDL as non-preferred
17. Yaz– Recommend status on the PDL as non-preferred
18. Zelapar-Recommend status on the PDL as non-preferred

Attachment 5

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.

NEWLY RELEASED GENERIC DRUGS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Cyclobenzaprine 5mg	Cyclobenzaprine 10mg/Preferred	Preferred
Finasteride	Proscar/Preferred	Non-Preferred
Pravastatin	Pravachol/Non-Preferred	Non-Preferred
Sertraline	Zoloft/Preferred	Non-Preferred
Simvastatin	Zocor/Preferred	Non-Preferred
Vandazole 0.75% gel	Metrogel Vaginal/Preferred	Non-Preferred
NEW DOSAGE FORMS		
Drug Name	**Brand Name/Status on PDL/RDL**	**PDL/RDL Recommendation**
Accuzyme SE	Accuzyme/Preferred	Preferred
Cardura XL	Cardura/Non-Preferred	Non-Preferred
Clarinex D	Clarinex/Preferred with Conditions	Preferred with Conditions
Humira Pen	Humira Kit/Preferred	Non-Preferred
Panafil SE	Panafil/Preferred	Preferred
Ultram ER	Ultram/Non-Preferred	Non-Preferred