Division of Medicaid
Office of the Governor
State of Mississippi
DUR Board Meeting

March 25, 2004

DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA

March 25, 2004

Welcome	**Tim Alford, MD**
Reading & Approval of Minutes Of November 20, 2003 DUR Board Meeting	**Lew Anne Snow, RN**
Update on Over-Utilization of Inhaled Beta-Agonists	**Sam Warman, R.Ph.**
Update on use of Generic Provider ID	**Sam Warman, R.Ph.**
Pharmacy Program Updates	**Judith Clark, R.Ph.**
2003 RDUR Statistics Review	**Lew Anne Snow, RN**
Black Box Warnings or Boxed Warning Update	**Sam Warman R.Ph.**
Suggested Interventions	**Sam Warman R.Ph.**
Next Meeting Information	**Tim Alford, MD**

NOVEMBER 20, 2003

Minutes of the November 20, 2003
Drug Utilization Review (DUR) Board Meeting

Members Attending: Tim Alford, M.D., Clarence Dubose, RPh, John Mitchell, M.D, Montez Carter, RPh, Joe McGuffee, RPh, Leigh Ann Ramsey, RPh, Sara Weisenberger, M.D.

Members Absent: Bob Broadus, RPh, Diana McGowan, RPh, Andrea Phillips, M.D., Cynthia Undesser, M.D.,

Also Present: Sam Warman, RPh, Lew Anne Snow, R.N., Kathleen Burns, R.N. -HID Rica Lewis-Peyton, Judith Clark, Terri Kirby, RPh, Bo Bowen, Phyllis Williams, Gay Gipson, R.N. – DOM, Otis Washington; Program Integrity - DOM

Clarence DuBose, RPh, called the meeting to order at 2:14 p.m.

Approval of minutes of last meeting (September 18, 2003): Joe McGuffee made a motion to accept the minutes as written. Leigh Ann Ramsey seconded the motion. All voted in favor of the approval.

Reports:
Update on the use of Generic Provider ID
Sam Warman presented data which indicated a 38% decrease in the use of the default provider ID after intervention letters were sent to those providers who utilized the default provider ID on greater than 40 % of their total prescriptions. Clarence DuBose asked HID to continue with this study. No recommendations were made.

Pharmacy Program Updates
Judith Clark, Pharmacy Bureau Director of the Division of Medicaid distributed handouts to the board members on the maximum units of inhalants allowed by DOM and a copy of OTC drugs currently covered by DOM. She stated that the P & T Committee voted to allow Prilosec OTC, Alavert, and Claritin Syrup to be covered without requiring prior authorization. Mrs. Clark reported that there is now a new section on the Division of Medicaid website designated specifically to Pharmacy Services. With the implementation of the Envision System on October 5, 2003 maximum units allowed for all medication went into effect. Medicaid provides up to a 34-day supply of medication to Medicaid beneficiaries. First Data Bank provides updated information regarding recommended maximum daily dosing and maximum units allowed to the Division of Medicaid. The maximum daily dose is determined according to the FDA approved and manufacturers suggested recommended daily dose. DOM allows 1.5 or 150% of the recommended maximum daily dose to be processed without triggering and over-ride. Maximum dose limits are utilized as a way to address abuse and over utilization of medications. A maximum dose over-ride request must be submitted to HID. Handouts were presented to the board regarding lab test billing forms, procedures and CPT codes necessary for patients being treated with lipid-lowering agents. DOM does not limit the number of times these lab tests may be performed. In order to be reimbursed for the lab test, the physician must first verify that the Medicaid beneficiary has at least one outpatient visit remaining, and when billing for the lab test, the correct form and CPT codes must be submitted to DOM. The physician's office or independent lab must also be CLIA (clinical laboratory improvement amendments) certified in order to receive payment. No recommendations were made.

Statin Utilization in Diabetes:
Sam Warman gave a report on the use of Statins in those Medicaid beneficiaries with a diagnosis of diabetes.
Recommendation: Sam Warman presented a letter, educational in content, which could be sent to physicians regarding Statin utilization. John Mitchell made a motion to accept this educational letter to the prescriber. Clarence Dubose seconded the motion. Motion approved.

Narcotic Prescribing Patterns:
The narcotic prescribing patterns of Medicaid providers was reviewed. A general discussion was offered on the need for monitoring "Cocktail Type "combinations of multiple narcotics. Judy Clark suggested that a study be repeated after Envision has been in effect for a full six months in order to collect sufficient data. No motion was made.

RDUR Criteria Recommendations:
Several new criteria recommendations which are used in the retrospective DUR process were presented. The RDUR criteria recommendations included:

- PPI Appropriate Dosing
- Dose Optimization
- Levitra –
  - High dose
  - Use with caution in patients with hepatic impairment
  - Use avoided in patients with congenital or acquired prolongation, or are receiving Class IA & III antiarrhythmics
  - Use in combination with nitrates or nitric oxide donors is contraindicated
  - Use in combination with an alpha blockers is contraindicated
  - Use with caution in patients with left ventricular outflow obstruction
  - Dosage may require adjustment in patients receiving ritonavir
  - Dosage may require adjustment in patients receiving erythromycin
  - Dosage may require adjustment in patients receiving indinavir
  - Dosage may require adjustment in patients receiving ketoconazole & itraconazole

- Crestor –
  - High dose
  - Contraindicated in patients with active liver disease
  - Dose should not exceed 5mg once daily in patients receiving concomitant cyclosporine
  - Concomitant use with gemfibrozil should be avoided
  - Dose should be initiated at 5mg once daily and should not exceed 10mg once daily for patients with severe renal impairment not on dialysis

- Tacrine –
  - Cardiovascular conditions
  - Use with caution in patients with hepatic impairment

Recommendation: Dr Mitchell made a motion to approve the suggested interventions. Joe McGuffee seconded the motion. All voted in favor of motion.

Suggested Interventions:

Sam Warman presented intervention recommendations. Each suggested intervention included the number of recipients identified during profile review as being at risk for the specific intervention. These suggested interventions included:

- Black Box Warning concerning ACE Inhibitor Use during Pregnancy
- Therapeutic Duplication of Muscle Relaxants as well as Overutilization of Soma
- Overutilization of Sedative Agents Ambien and Sonata
- Therapeutic Duplication of Atypical Antipsychotics – 90 days
- The Overutilization of Narcotic Agents
- The Overutilization of Anxiolytic agents
- Therapeutic Duplication of Anxiolytic Agents
- Overutilization of Inhaled Beta-Agonists
- Overutilization of Stimulants
- Underutilization of Lipid Lowering Agents

Recommendation: Dr Mitchell made a motion to approve the suggested interventions. Joe McGuffee seconded the motion. All voted in favor of motion.

Focused RDUR on Long Term Care Beneficiaries and Under 21 Groups:
Sam Warman presented information regarding a possible focused RDUR study on long term care beneficiaries and beneficiaries less than 21 years of age. John. Mitchell M.D. stated consultant pharmacists currently perform monthly reviews for beneficiaries in a long term care facility. Dr. Mitchell stated a letter as recommended would not be necessary or useful. No motion was made.

Black Box Warnings:
Sam Warman presented black box warnings issued by the FDA concerning the following:

- Accutane (isotretinoin) capsules
- Advair (fluticasone propionate/salmetrol) inhalation powder

Meeting Dates for 2004:
Discussion was held concerning the dates for DUR Board meetings in 2004. The proposed dates for 2004 DUR Board meetings are:

- March 25, 2004
- June 24, 2004
- September 23, 2004
- November 18, 2004

All voted in favor of approval.

Next Meeting Information:
Dr. Alford reminded the Board of the next meeting on March 25, 2004 at 2:00pm.
There being no other business, Dr. Alford asked for a motion to adjourn the meeting. Montez Carter made a motion to adjourn. John Mitchell seconded the motion. The meeting was then adjourned at 3:40p.m.

Respectfully submitted;
Health Information Designs

Update on Overutilization
Of
Beta Agonists

Introduction

The Mississippi Drug Utilization Review (DUR) Board approved a criterion recommendation and prescriber letter for an intervention concerning the over-utilization of inhaled Beta Agonists

Methodology

Paid claims data are forwarded from ACS to Health Information Designs (HID) for review and evaluation. The DUR Board, Division of Medicaid (DOM), and HID developed the criterion for the evaluation. In order for a claim exception to occur, a beneficiary has to have at least a 60 day supply in 90 days. Once this happens, the system does a dose calculation. If the beneficiary exceeds the dose limit of 1.2 in the three months, the over-utilization of inhaled beta agonist criterion hits. The system calculates the maximum dose by mg/dose. The inhalers are calculated by the maximum inhalations allowed per day and then converted to a mg/dose.

For this update, the time span used was July 2003 through January 2004. Claims data were evaluated against the criterion and cases were identified for review by a HID clinical pharmacist.

Approved educational intervention letters with attached response forms were mailed to prescribers for identified recipients. A sample copy of the intervention letter can be found at the end of this update. The response form asks the prescriber to indicate any action taken in response to the intervention letter. Response forms were returned to HID for review and evaluation.

Results

A total of 247 recipients were identified who appeared to be over-utilizing inhaled beta-agonists. Table 2 summarizes the profile review and letter generation process.

Drug History Profile Review and Letter Interventions	Recipient profiles/intervention letters	Intervention letters not mailed
Number of recipient profiles with criteria exceptions selected for review	225	
Recipient profiles selected for letter intervention based on review guidelines	134	
Intervention letters not mailed due to the use of the default prescriber number		19
Intervention letters not mailed due alert insignificant—all other		6
Intervention letters not mailed due to returned mail—hosp. & DIR. DEA's-can't provide MD info		21
Intervention letter not sent, incomplete MD info, data entry only		1
Total number of intervention letters	87 (10 duplicates)	

After profiles were reviewed, 77 unique recipients were available for intervention. A total of 77 unique prescriber intervention letters were generated based on these 77 recipients.

As of 2/4/04,14 responses have been received equaling nearly an 18% response rate. Table 3 summarizes the prescriber responses.

Table 3

Response	Number of responses
Is my patient but have not seen in most recent 6 months	2
Patient is no longer under this physician's care	1
Patient has appointment to discuss drug therapy problem	2
Patient never under this physician's care	3
Physician will reassess and modify drug therapy	1
Tried to modify therapy, symptoms recurred	1
Physician feels problem is insignificant, no change in tx	1
Physician tried to modify therapy, patient non-cooperative	1
Physician response does not discuss drug therapy conflict	1
MS saw patient only once in ER or as On-call MD	1

Discussion

The focus of this review is to alert for possible worsening asthma through possible over-utilization of inhaled beta agonists. This criterion applies only to beneficiaries who receive inhaled beta-agonists AND have a respiratory disease diagnosis. Thus, this criterion is not specific for asthma only. In fact, beneficiaries who may appear as an exception may have other respiratory diagnosis such as COPD, emphysema, etc. It's important to note that many of the physician responses show 5 of the 14 responses address that many of them have or will try to modify the drug therapy.
NIH guidelines do suggest that in the long-term control of asthma that many asthmatics may benefit from the addition of an inhaled corticosteroid and /or long-acting inhaled beta-agonist, mast cell stabilizer, or leukotriene modifier. This criterion doesn't suggest to do so but simply alert that a beneficiary's asthma may not be controlled ideally due to more frequent dispensing or large amounts of the inhaled beta-agonist.
This criterion has been changed over the years since its creation in 1998. In the beginning, it required a beneficiary to exceed a 30 days supply which is more aggressive.
However it is now set to exceed a 60 day supply.

Conclusion

Effective asthma management is essential to reducing hospitalizations and increasing the quality of life of those affected. Although this criterion does not solely address the asthma diagnosis, it does address the probable uncontrolled or worsening asthma condition. The responses to the intervention letters seem to indicate that this criterion is effective in at the

Utilization of Default/Generic Provider ID

TOP Prescribers for Month 12/2003 for Program ALL

Prescribers	Description	Rx Count	Dollar Total	Dollar/Rx
19999	DEFAULT PROVIDER-VOID VOID	168,293	$9,771,116.33	$58.06
xxxxxxx	xxxxxxx	15,818	$980,305.11	$61.97
1999999	ALL NINES, PROVIDER	8,573	$511,637.18	$59.68
xxxxxxx	xxxxxxx	116	$236,346.23	$2,037.47
xxxxxxx	xxxxxxx	3,620	$222,908.87	$61.58
xxxxxxx	xxxxxxx	1,275	$189,018.95	$148.25
xxxxxxx	xxxxxxx	895	$175,251.52	$195.81
199999	n/a	3,055	$166,084.79	$54.36
xxxxxxx	xxxxxxx	2,593	$149,302.52	$57.58
xxxxxxx	xxxxxxx	2,330	$136,541.22	$58.60
xxxxxxx	xxxxxxx	2,220	$122,763.10	$55.30
xxxxxxx	xxxxxxx	1,837	$121,614.10	$66.20
xxxxxxx	xxxxxxx	1,357	$121,471.07	$89.51
xxxxxxx	xxxxxxx	2,204	$119,300.01	$54.13
xxxxxxx	xxxxxxx	248	$116,996.27	$471.76
xxxxxxx	xxxxxxx	2,154	$114,572.96	$53.19
xxxxxxx	xxxxxxx	1,046	$112,661.91	$107.71
xxxxxxx	xxxxxxx	1,671	$111,009.53	$66.43
xxxxxxx	xxxxxxx	1,548	$108,983.64	$70.40
xxxxxxx	xxxxxxx	2,378	$97,933.77	$41.18

Updated data run 9/1/03 to 11/30/03 shows 128 pharmacies utilizing the generic prescriber number ≥ 40%.
74 pharmacies which received letters in August 2003 still utilize the generic prescriber number ≥ 40%.

Cumulative Summary Table

REPORT PERIOD: December 1, 2002 – November 30, 2003

DUR Cycle	ICER date	CASES IDENTIFIED	LETTERS SENT	NUMBER of PHYSICIAN REPLIES	PHYSICIAN REPLY RATE (%)
DECEMBER	12/13/2002	585	546	117	21%
JANUARY	01/08/2003	755	658	154	23%
FEBRUARY	02/03/2003	587	571	145	25%
MARCH	03/05/2003	704	549	130	24%
APRIL	04/07/2003	387	342	88	26%
MAY	05/07/2003	362	310	77	25%
JUNE	06/05/2003	227	173	48	28%
JULY	07/07/2003	422	346	80	23%
AUGUST	08/07/2003	377	242	52	21%
SEPTEMBER	09/04/2003	702	556	113	20%
OCTOBER	10/07/2003	701	559	3	1%
NOVEMBER	11/22/2003	708	533	7	1%
TOTAL	**2003**	**6517**	**5385**	**1014**	**20%**

DISTRIBUTION OF CASES

The potential drug therapy problems reviewed in the DURbase3™ Therapeutic Drug Utilization Review program fall into four categories. The categories of drug therapy problems and percentage of cases in each category identified during the reporting period were as follows:

Drug-Disease Interactions 13%
Patients receiving a drug that may worsen or precipitate a medical condition.

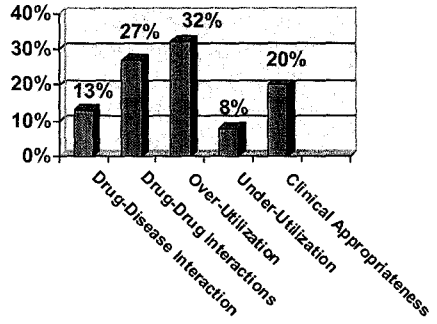
Drug-Drug Conflict 27%
Patients receiving two or more drugs that, when taken together, may interact and produce unpredictable and undesirable effects.

Over-Utilization 32%
Patients taking medications in apparently excessive doses or for excessive lengths of time.

Under-Utilization 8%
Patients taking medications for the treatment of chronic conditions at levels below the normal minimum effective dose.

Clinical Appropriateness 20%
Therapeutic appropriateness is defined as patients who are NOT taking medications for the treatment of a disease in which the medication is current practice standard of care. Cost appropriateness and appropriate use of generics are also included in this category.

Type of Drug Therapy Problems for 2003



Health Information Designs, Inc
"Using medication Information cost effectively"

P.O. Box 320506
Flowood, MS 39232

601-709-0000
800-355-0486
FAX 800-459-2135

date

[adrs1]
[adrs2]
[adrs3]
[adrs4]

Dear Pharmacist-in-Charge:

Federal and State regulations require the Division of Medicaid to conduct retrospective drug utilization reviews (DUR). The Division of Medicaid contracts with Health Information Designs to conduct these reviews. The objectives of DUR are:

- Prevent under-utilization
- Prevent over-utilization
- Prevent iatrogenic effects and adverse drug reactions
- Prevent contraindicated combination use
- Prevent drug therapy contraindicated by diagnosis

Without prescriber identification numbers on pharmacy claims this cannot be adequately performed. In a recent review, approximately 60% of the claims used the default/generic prescriber identification number.

The following information was obtained during the period of 10/1/2003-1/31/2004

Number of Medicaid prescriptions dispensed from your pharmacy	**[numrxs]**
Percentage of Medicaid claims from your pharmacy using the generic/default provider number	**[perc]**
State-wide Median	**16.5%**

The Division of Medicaid's policy for identifying prescribers on pharmacy claims is enclosed. We ask that you take immediate steps to ensure accurate provider information on claims submitted for payment. Accurate prescriber identification of the prescription issuer is required.

Non-compliance may result in termination of POS privileges.

If you have any questions about this letter, please contact Samuel Warman, R.Ph. at 1-800-355-0486, Ext 100.

Sincerely,

Samuel Warman, R.Ph.
Health Information Designs, Inc.
Enclosure

Health Information Designs, Inc
"Using medication Information cost effectively"

P.O. Box 320506
Flowood, MS 39232

601-709-0000
800-355-0486
FAX 800-459-2135

Reprinted from the Mississippi Medicaid Bulletin April 2003

Identification of Prescribers on Pharmacy Claims

The Division of Medicaid is reviewing pharmacy claims for accuracy. An analysis of the Medicaid pharmacy claims determined that a substantial number of pharmacy providers submitted claims with either an invalid prescriber number or an unknown prescriber number such as 0019999 or 1999999.

In order to decrease the use of the "generic" prescriber number for pharmacy claims, the Division of Medicaid is implementing the use of the following procedures for indicating the prescriber on prescription claims to assist pharmacists in submitting accurate claims information to DOM:

1. If the prescriber's name and provider number are listed on the Prescribing Providers Lists (Mississippi, Alabama, Arkansas, Louisiana, and Tennessee), this provider number should be filed on the pharmacy claim submitted for payment by Medicaid.

2. If the prescriber's name and provider number are not listed on the Prescribing Providers Lists, the prescriber's office should be contacted by the pharmacy to acquire the provider number. If the issuer of the prescription does not participate in Medicaid as a provider of services, the 0019999 prescriber number should be entered to the pharmacy claim.

3. If the prescriber is a member of a clinic from which the prescription was issued, but the individual physician/nurse practitioner does not have his or her own prescriber number, determine if the clinic's provider number is contained in the listing. If so, use the clinic's provider number.

4. If the prescription is issued at a hospital or ER for outpatient dispensing and that location has a provider number in the Prescribing Providers lists, utilize this number or the prescriber's provider number.

5. If no prescriber identification number is available following a good faith effort by the pharmacy staff to obtain one, the 0019999 number may be utilized.

The pharmacy is responsible for maintaining accurate and current prescriber identification capability accessible to pharmacy employees. When the utilization of the 0019999 number becomes substantial, the pharmacy provider should again attempt to obtain a Medicaid provider number for prescribers.

In order to receive a current Prescribing Provider List you may contact the fiscal agent. The list is also available at http://www.dom.state.ms.us/Provider/Publications/publications.html.

Accurate prescriber identification of the prescription issuer is required; non-compliance may result in termination of POS privileges.

Office of the Governor
Division of Medicaid
[[ADDRESS]

Administered by Health Information Designs, Inc
PO Box
[ADDRESS]

[TODAY]

[adrs1]
[adrs2]
[adrs3]
[adrs4]

DEAR [Dr. XXXXXX]:

In compliance with the OBRA '90 federal legislation, state Medicaid agencies are mandated to institute Retrospective Drug Utilization Review Programs (RDUR). The program's goal is to ensure that Medicaid patients receive optimal drug therapy at the lowest reasonable cost. One way to achieve this goal is to identify potential drug therapy problems that may place patients at risk, particularly if multiple providers are identified. This RDUR program is informational in nature and allows you to incorporate the information provided into your continuing assessment of the patient's drug therapy requirements.

[alert_msg] During a recent review of the enclosed drug history profile, *it was noted that your patient,* **[John] [Smith]**, *has a diagnosis of asthma and has submitted claims for excessive amounts of* **[drug_a_name].** *Additionally, infrequent or no claims have been submitted leading to suspicion of sub-optimal dosing of long-term controller medications over the past several months. We routinely notify practitioners of suspected excessive use to ensure the patient is following the regimen as intended.*

We have enclosed the historical profile and an asthma management card summarizing NIH guidelines for your evaluation and consideration. Since we are interested in feedback about our program from providers, we would appreciate learning of your assessment of this information. Please complete the response form on the reverse side of this letter and return it in the enclosed envelope or fax it to the number below.

At the bottom of this letter are the specific prescriptions attributed to you by the dispensing pharmacy. In addition, if multiple physicians are involved, each will receive this information. Thank you for your professional consideration.

RX #(s): [rx_no_a]

Sincerely,

W. Murray Yarbrough M.D.

W. Murray Yarbrough, M.D.
Medical Director

Case#: [case_no]
Enclosures

Administered by Health Information Designs, Inc.
1550 Pumphrey Ave.
Auburn, AL 36832-9956
(800)225-6998 x 3033 Fax(334)502-6589

Office of the Governor
Division of Medicaid
[[ADDRESS]

Administered by Health Information Designs, Inc
PO Box
[ADDRESS]

PRESCRIBER RESPONSE

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s)_____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy, however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:

_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___.(Please provide a fax number if available_____-_____-_____.)

Comments: _____
_____
_____
_____

[adrs1] Case# [case_no]
Letter Type [letter_type]
[alert_msg]
[criteria]

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Auburn, AL 36832-9956
(800)225-6998 x 3033 Fax(334)502-6589

Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment

	Symptoms/Day Symptoms/Night	PEF or FEV_1 PEF Variability	Daily Medications
Severe Persistent	Continual Frequent	≤ 60% >30%	• **Preferred treatment:** **- High-dose inhaled cortisosteroids AND** **- Long-acting inhaled beta$_2$-agonists** AND, if needed, - Corticosteroid tablets or syrup long-term (2mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Moderate Persistent	Daily >1 night/week	>60% - < 80% >30%	• **Preferred treatment:** **- Low-to-medium dose inhaled corticosteroids and long-acting inhaled beta$_2$-agonists.** • Alternative treatment (listed alphabetically): - Increase inhaled corticosteroids within medium-dose range OR - Low-to-medium dose inhaled corticosteroids and either leukotriene modifier or theophylline. ..... If needed (particularly in patients with recurring severe exacerbations): • **Preferred treatment:** **- Increase inhaled corticosteroids within medium-dose range and add long-acting inhaled beta$_2$-agonists.** • Alternative treatment: - Increase inhaled corticosteroids within medium-dose range and add either leukotriene modifier or theophylline.
Mild Persistent	>2/week but < 1x/day >2 nights/month	≥ 80% 20-30%	• **Preferred treatment:** **- Low-dose inhaled corticosteroids.** • Alternative treatment (listed alphabetically): cromolyn, leukotriene modifier, nedocromil, OR sustained-release theophylline to serum concentrations of 5-15 mcg/mL
Mild Intermittent	≤2 days/week ≤2 nights/month	≥ 80% < 20%	• No daily medication needed. • Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic coticosteroids is recommended.

All Patients	• Short-acting bronchodilators: 2–4 puffs **short-acting inhaled beta$_2$-agonists** as needed for symptoms. • Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed. • Use of short-acting beta-agonists > 2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.

Step down

Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.

Step Up

If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control..

Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
- Minimal or no exacerbations
- No limitations on activities; no school/work missed
- Maintain (near) normal pulmonary function
- Minimal use of short-acting inhaled beta$_2$-agonist (< 1x per day, < 1 canister/month
- Minimal or no adverse effects from medications.

Note

- The stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV_1 is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g. allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service•National Institutes of Health•National Heart, Lung and Blood Institute NIH Publication No. 97-4051 June 2002

Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment

Assess Severity: Chronic Features Before Treatment or Upon Loss of Control			
	Symptoms/Day **Symptoms/Night**	**PEF or FEV_1** **PEF Variability**	Daily Medications
Step 4 Severe Persistent	Continual Frequent	≤ 60% >30%	• **Preferred treatment:** **- High-dose inhaled cortisosteroids** **AND** **- Long-acting inhaled beta$_2$-agonists** AND, if needed, - Corticosteroid tablets or syrup long-term (2mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Step 3 Moderate Persistent	Daily >1 night/week	>60% - < 80% >30%	• **Preferred treatment:** **- Low-to-medium dose inhaled corticosteroids and long-acting inhaled beta$_2$-agonists.** • Alternative treatment (listed alphabetically): - Increase inhaled corticosteroids within medium-dose range OR - Low-to-medium dose inhaled corticosteroids and either leukotriene modifier or theophylline. ..... If needed (particularly in patients with recurring severe exacerbations): • **Preferred treatment:** **- Increase inhaled corticosteroids within medium-dose range and add long-acting inhaled beta$_2$-agonists.** • Alternative treatment: - Increase inhaled corticosteroids within medium-dose range and add either leukotriene modifier or theophylline.
Step 2 Mild Persistent	>2/week but < 1x/day >2 nights/month	≥ 80% 20-30%	• **Preferred treatment:** **- Low-dose inhaled corticosteroids.** • Alternative treatment (listed alphabetically): cromolyn, leukotriene modifier, nedocromil, OR sustained-release theophylline to serum concentrations of 5-15 mcg/mL
Step 1 Mild Intermittent	≤2 days/week ≤2 nights/month	≥ 80% < 20%	• No daily medication needed. • Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic coticosteroids is recommended.

Quick Relief	
All Patients	• Short-acting bronchodilators: 2–4 puffs **short-acting inhaled beta$_2$-agonists** as needed for symptoms. • Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed. • Use of short-acting beta-agonists > 2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.

Step down

Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.

Step Up

If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control..

Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
  Minimal or no exacerbations
  No limitations on activities; no school/work missed
- Maintain (near) normal pulmonary function
- Minimal use of short-acting inhaled beta$_2$-agonist (< 1x per day, < 1 canister/month
- Minimal or no adverse effects from medications.

Note

- The stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV_1 is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g. allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service•National Institutes of Health•National Heart, Lung and Blood Institute NIH Publication No. 97-4051 June 2002

Office of the Governor
Division of Medicaid

Drug Utilization Review Program

Administered by Health Information Designs, Inc.
PO Box 320506
Flowood, MS 39232
(800) 355-0486 Fax (800) 459-2135

[TODAY]

[adrs1]
[adrs2]
[adrs3]
[adrs4]

DEAR [tadrs1]:

Health Information Designs, Inc. (HID) is the pharmacy benefits management/drug utilization review organization contracted with the Mississippi Division of Medicaid (DOM) to review pharmacy services provided to Medicaid beneficiaries. Under this contract, we seek to ensure that Medicaid beneficiaries receive appropriate and cost effective drug therapy. One way to achieve this goal is to identify potential drug therapy problems that may place patients at risk, particularly if multiple providers are identified. **This letter is educational in nature and allows you to incorporate the information provided into your continuing assessment of the patient's drug therapy.**

During a recent review of the enclosed drug history profile, *it was noted that your patient,* **[t1d0-recip-fst-nm] [t1d0-recip-lst-nm]**, *may be receiving excessive amounts of* **[drug_a_name]**. We routinely notify practitioners of suspected excessive use to ensure the patient is using the regimen as intended. The enclosed historical profile is provided for your evaluation and consideration. In presenting this information to you, we recognize that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware.

The success of the DUR program is enhanced by the two-way exchange of information. Therefore, at your convenience, we would appreciate learning of your assessment of this information and of any action taken in response to this notice. Although your participation in this program is voluntary, we find your feedback helpful in adjusting our program to address clinically important problems. Please complete the response form on the reverse side of this letter and return it in the enclosed envelope or fax it to the number below.

At the bottom of this letter are the specific prescriptions attributed to you by the dispensing pharmacy. In addition, if multiple physicians are involved, each will receive this information. Thank you for your professional consideration.

RX #(s): [rx_no_a]

Sincerely,

W. Murray Yarbrough M.D.

W. Murray Yarbrough, M.D.
Medical Director
Health Information Designs, Inc.

Case#: [case_no]
Enclosures

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PRESCRIBER RESPONSE

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s) _____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy; however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:

_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___. (Please provide a fax number if available_____-_____-_____.)

Comments: _____
_____
_____
_____

[adrs1] Case# [case_no]
Letter Type [letter_type]
[alert_msg]
[criteria]

Boxed Warning Update

Code of Federal Regulations definition for Black Box:

Citation: Title 21 CFR 201.57 Section E

(e) Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the "Indications and Usage" section of labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problem, particularly those that may lead to death or serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

Viramune (nevirapine)

Audience: Infectious disease and other healthcare professionals

Boehringer Ingelheim and FDA notified healthcare professionals of new safety information added to the WARNINGS and Boxed Warning for VIRAMUNE. Severe, life-threatening, and in some cases fatal hepatotoxicity, including fulminant and cholestatic hepatitis, hepatic necrosis and hepatic failure, has been reported in patients treated with VIRAMUNE. These events are often associated with rash. Women, and patients with higher CD4 counts, are at increased risk of these hepatic events. Women with CD4 counts >250 cells/mm^3, including pregnant women receiving chronic treatment for HIV infection, are at considerably higher risk of these events. Prodromal signs and symptoms, risk information and monitoring recommendations have been added to the labeling.

Suggested Interventions
March 25, 2003 4

- **Inappropriate Therapy for the Elderly**

Long half-life Benzodiazepine Anxiolytics
"Benzodiazepine anxiolytic agents with long half-lives should be avoided in the elderly due to their increased sensitivity to these agents. Chronic dosing of these agents may result in accumulation of the parent compound and the active metabolite causing prolonged sedation and increased risk of falls/fractures. Anxiolytics with short to intermediate half-lives such as oxazepam and lorazepam are recommended as alternatives"
Initial Criteria Exception Report Count—560 beneficiaries

Long half-life Benzodiazepine Sedatives
"Benzodiazepine sedative/hypnotics with long half-lives should be avoided in the elderly due to their increased sensitivity to these agents. Chronic dosing of these agents can result in accumulation of the parent compound and the active metabolite causing prolonged sedation and increased risk of falls/fractures. Sedative/hypnotics with short or intermediate half-lives such as zolpidem, zaleplon or temazepam are recommended alternatives and are intended for short-term use"
Initial Criteria Exception Report Count—14

Barbiturate Sedative Hypnotics
"Barbiturate sedative/hypnotics are associated with rapid development of tolerance, psychological and physical dependence as well as withdrawal. The elderly may have increased sensitivity to barbiturates resulting in prolonged sedation, increasing the risk of falls/fractures. Sedative/hypnotics with short or intermediate half-lives, such as zaleplon, zolpidem, estazolam, and temazepam are alternative agents with more favorable adverse effect profiles and are intended for short-term use"
Initial Criteria Exception Report Count—19

Tertiary Amine TCA
"Tertiary amine tricyclic antidepressants should be used with caution in the elderly with depressive symptoms. These agents have significant anticholinergic side effects and are sedating increasing the risk of falls/fractures. Secondary amine tricyclic antidepressants, nortriptyline and desipramine, selective or non-selective serotonin reuptake inhibitor antidepressants are alternative agents with more favorable adverse effect profiles"
Initial Criteria Exception Report Count—1,774

Sonata and Ambien
"Elderly and debilitated patients appear to be more sensitive to the effects of hypnotics, therefore the recommended dose of Ambien (zolpidem) and Sonata (zaleplon) is 5mg. Impaired motor and /or cognitive performance appears to be dose-related"
Initial Criteria Exception Report Count—1,109

MISSISSIPPI MEDICAID
1ST QUARTER ACTIVITY STATISTICAL REPORT - YEAR 2004

	January	SUM		AVERAGE
Date Processed	1/20/2004			
# Claims Processed	989969	989,969		989,969
# Criteria Exception Hits (or # Potential Drug Therapy Problems)	131528	131,528		131,528
# Unique Patients with Hits	74915	74,915		74,915
PROFILES				
PRINTED/REVIEWED	1107	1,107		1,107
REJECTED	212	212		212
CASE INFORMATION				
IDENTIFIED	998	998		998
CASE RATE	90%	90%		90%
LETTER GENERATION				
VALID PRESCRIBER ID	1196	1,196		1,196
PHARMACY CALLS	0	0		0
TOTAL GENERATED	1196	1,196		1,196
DELETED GENERIC PRESCRIBER ID	173	173		173
DELETED IN QA	268	268		268
# PRESCRIBER LETTERS MAILED	755	755		755
# PRESCRIBER RESPONSES RECEIVED	0	0		0
RESPONSE RATE	0%	0%		0%
DISTRIBUTION OF CASES By Problem Type			Percentage	
DRUG/DISEASE INTERACTIONS	184	184	18%	184
DRUG/DRUG CONFLICTS	163	163	16%	163
OVER-UTILIZATION	338	338	34%	338
POSSIBLE NON-COMPLIANCE	62	62	6%	62
CLINICAL APPROPRIATENESS	251	251	25%	251
		998	100%	
LETTER FOLLOW UP				
800 DUR CALLS, PROFILE FAXES, ETC.	0	0		0
PRESCRIBER REQUESTS FOR INFO	0	0		0
# PROFILE REFERRALS to SURS Program	0	0		0