South Dakota Department of Social Services

Medicaid P&T Committee Meeting

September 10, 2010

DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES
700 Governors Drive
Pierre, South Dakota 57501-2291
(605) 773-3495
FAX (605) 773-5246

SOUTH DAKOTA
MEDICAID P&T COMMITTEE MEETING
AGENDA

Friday, September 10, 2010
1:00 – 3:00 PM

DDN Locations:
Sioux Falls
University Center
Room UC282S
2205 Career Avenue

Pierre
Capitol Building
DDN Room B
500 E Capitol

Rapid City
Rapid City Regional Hospital
353 Fairmont Blvd/Edu. Services

Call to Order

Approval of Minutes of Previous Meeting

Annual Prior Authorization Update

Review of Top 15 Therapeutic Categories/Top 25 Drugs

Patent Expirations and Pipeline Information

Old Business
- **Medications used to treat ADD/ADHD**
- **Narcotics**
- **Prior Authorization of High Cost/Low Utilization Drugs**
- **Metozolv ODT**

New Business
- **Statins**
- **Soma 250**
- **Multaq**
- **Xyrem**

Oral Presentations and Comments by Manufacturers' Representatives

Next Meeting Date/Adjournment

Minutes of the June 11, 2010
Pharmacy & Therapeutics (P&T) Committee Meeting
SD Department of Social Services, Medical Services Division

Members present
Dana Darger, R.Ph; Bill Ladwig, R.Ph; Rick Holm, M.D.; Debra Farver, PharmD.; Verdayne Brandenburg, M.D.; Willis Sutliff, M.D.; Galen Goeden, R.Ph; James Engelbrecht, M.D.

Members absent
Timothy Soundy, M.D.; Dennis Hedge, PharmD.

DSS staff present
Mike Jockheck, RPh.

HID staff present
Candace Rieth, Pharm.D.

Administrative Business
The P&T meeting was called to order by D. Darger at approximately 1:05pm. The minutes of the March 12, 2010 meeting were presented. B. Ladwig made a motion to approve. V. Brandenburg seconded the motion. The motion was approved unanimously. B. Ladwig made a motion to review all current medications on prior authorization (forms and criteria) annually. J. Engelbrecht seconded the motion. The motion was approved unanimously. W. Sutliff made a motion that information regarding patent expirations and pipeline medications be included in the quarterly P&T packet. D. Farver seconded the motion. The motion was approved unanimously.

Prior Authorization Statistics
C. Rieth presented an overview of the prior authorization (PA) activity for April 2010. There were a total of 1,912 PAs processed in the month of April, with 99.79% of those requests responded to in less than 8 hours. There were 1,648 (86%) requests received electronically and 264 (14%) requests received by fax. In response to a request from the committee, C. Rieth presented the number of approvals and denials, by form type, for the faxed (manual) PA requests.

Analysis of the Top 15 Therapeutic Classes
C. Rieth reviewed the Top 15 Therapeutic Classes by total cost of claims from 01/01/2010 – 03/31/2010. The top five classes were antipsychotics, cerebral stimulants, amphetamines, beta-adrenergic agonists, and antidepressants. The top 15 therapeutic classes make up 44.70% of total claims.

ADD/ADHD Review
C. Rieth presented clinical information and data for medications used to treat ADD/ADHD. The committee suggested that a list of prescribers be included in the next review. The committee also requested step therapy information from other state Medicaid programs. Dr. Carroll Isburg spoke against prior authorization of medications used to treat ADD/ADHD. Dr. Jerry Blake spoke against prior authorization of medications used to treat ADD/ADHD. John Brokars, representing Lilly, discussed prescribing information for Strattera. Phyllis Arends, representing NAMI, spoke against prior authorization of medications used to treat ADD/ADHD. J. Engelbrecht made a motion to review this information at the next meeting. R. Holm seconded the motion. The motion was approved unanimously.

Suboxone/Subutex

C. Rieth presented clinical information and data for Suboxone and Subutex. Dave Helgeland, representing SDSU College of Pharmacy and the RDUR committee, discussed certification of Suboxone/Subutex prescribers. G. Goeden made a motion to place Suboxone and Subutex on prior authorization. V. Brandenburg seconded the motion. The motion was approved unanimously.

Opiate Agonist Review

C. Rieth presented clinical information and data for the opiate agonists. There was no public comment. A motion was made by B. Ladwig to further review opiate agonists including a list of products that are appropriate for prior authorization. W. Sutliff seconded the motion. The motion was approved unanimously.

High Cost/Low Utilization Drugs

C. Rieth presented a table showing high cost/low utilization drug utilization for 2009. There was no public comment. J. Engelbrecht made a motion to review this topic further, including research on specialty pharmacies and their place in SD Medicaid. R. Holm seconded the motion. The motion was approved unanimously.

The next meeting date is scheduled for September 10, 2010. The location will be updated on the website as soon as possible. A motion was made by B. Ladwig at 3:05pm to adjourn the SD Medicaid P&T meeting. D. Darger seconded. Motion passed unanimously and the meeting was adjourned.

ALTABAX PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a prescription for Altabax must first try and fail MUPIROCIN.

- **Patients must use generic mupirocin for a minimum of 5 days for the trial to be considered a failure.**
- **Patients diagnosed with MRSA may be approved to use Altabax first-line.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of mupirocin in the last 90 days	Was mupirocin trial for at least 5 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication to mupirocin: (provide description below):	
Medical Justification for use of Altabax without trial of mupirocin:	
Physician Signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

AMBIEN CR PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients have a trial of zolpidem prior to receiving a PA for Ambien CR.

- **Patients must use generic zolpidem for a minimum of 14 days for the trial to be considered a failure.**
- **Previous usage of Ambien CR does not count as a trial.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Dosage: (must be completed)

Diagnosis for this request:

Qualifications for coverage:

❑ Failed trial of zolpidem in the last 365 days	Was zolpidem trial for at least 14 days? ❑ YES ❑ NO	Zolpidem Dose:
		Zolpidem Frequency:

Adverse Reaction (attach FDA Medwatch form) or contraindication to zolpidem: (provide description below):

Medical Justification for use of Ambien CR without trial of zolpidem:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

AMRIX/FEXMID PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients have a trial of cyclobenzaprine before receiving a PA for Amrix or Fexmid.

- **Cyclobenzaprine does not require a PA**
- **Patient must fail therapy on generic cyclobenzaprine before a PA will be considered.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Medication Requested: □ **AMRIX** □ **FEXMID**	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

❑ Failed cyclobenzaprine therapy	Start Date: Dose: End Date: Frequency:

Adverse Reaction (attach FDA MedWatch form) or contraindication to inactive ingredients in cyclobenzaprine: (provide description below):

Medical Justification for use of Amrix or Fexmid without trial of cyclobenzaprine:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

ANTI-HISTAMINE PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving anti-histamines must use **Loratadine*** as first line.

- **Loratadine OTC and cetirizine may be prescribed WITHOUT prior authorization. Loratadine and cetirizine are covered by Medicaid when prescribed by a physician.**
- **Prior authorization is NOT required for patients < 13 years of age.**
- **Patients must use loratadine and cetirizine for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute failure.**
- **Patients are encouraged to try and fail generic loratadine and cetirizine prior to receiving a leukotriene modifier or intranasal steroid to treat allergic rhinitis.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

REQUESTED DRUG (PLEASE CHECK)**:** ❑ Allegra ❑ Allegra-D ❑ Claritin Rx ❑ Clarinex ❑ Clarinex –D ❑ Claritin-D Rx ❑ Zyrtec ❑ Zyrtec-D ❑ Fexofenadine	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

❑ Failed loratadine ❑ Failed cetirizine	Was trial for at least 14 days? ❑ YES ❑ NO	Dose: Frequency:

Adverse Reaction (attach FDA Medwatch form) to loratadine or cetirizine or contraindicated: (provide description below)

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

ARB PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving an ARB first try and fail one ACE Inhibitor. A PA may be given for one of the following reasons:

- **The patient has been stable on an ARB for greater than 60 days**
- **Patient has an additional diagnosis (such as COPD or RF) that precludes a trial with an ACE Inhibitor**
- **The provider has additional medical justification that supports first-line therapy with an ARB**

ARBs include: Atacand, Atacand/HCT, Avapro, Avalide, Benicar, Benicar/HCT, Cozaar, Diovan, Diovan/HCT, Hyzaar, Micardis, Micardis/HCT, Teveten, Teveten/HCT.

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy)

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy)

PHYSICIAN NAME:		PHYSICIAN MEDICAID ID NUMBER:
City:	FAX: ( )	Phone: ( )

Part III: TO BE COMPLETED BY PHYSICIAN

REQUESTED DRUG:	**Requested Dosage:** (must be completed)
	Diagnosis for this request:

Qualifications for coverage:

Has patient been stable on requested ARB for more than 60 days? ❑ YES ❑ NO

Has patient tried and failed an ACE Inhibitor? ❑ YES ❑ NO

Does patient have a diagnosis of COPD or acute/chronic renal failure? ❑ YES ❑ NO

Medical Justification for use of an ARB without a trial of an ACEI:

Physician Signature: Date:

Part IV: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

CALOMIST/NASCOBAL
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for CaloMist or Nascobal must try injectable B-12 as first line therapy.

- **Injectable B-12 does not require a prior authorization.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:			Diagnosis for this request:	
□ Failed Therapy	Dose	Frequency	Start Date	End Date
□ Medical Justification for use of CaloMist or Nascobal without a trial of injectable B-12:				
PHYSICIAN SIGNATURE:				DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

DISPENSE AS WRITTEN PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving brand name medications (with a generic available) first try and fail the generic product. A PA may be given for one the following reasons:

- **The generic product was not effective**
- **There was an adverse reaction with the generic product**
- **The generic product is not available**

If a drug is on the South Dakota Narrow Therapeutic Index list, the drug is excluded from the PA requirement

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy)

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy)

PHYSICIAN NAME:		PHYSICIAN MEDICAID ID NUMBER:
City:	FAX: ( )	Phone: ( )

Part III: TO BE COMPLETED BY PHYSICIAN

REQUESTED BRAND NAME DRUG:	**Requested Dosage:** (must be completed)
	Diagnosis for this request:

Qualifications for coverage:

Has treatment with the generic equivalent been attempted? ❑ YES ❑ NO

If yes, please indicate the reason for discontinuation below.

❑ Adverse reaction to the generic equivalent (FDA Medwatch form is required – form is available at www.fda.gov or www.hidsdmedicaid.com)

❑ Contraindication of generic equivalent (please provide medical justification in this space):

Physician Signature: Date:

Part IV: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

PRIOR AUTHORIZATION REQUEST FORM
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

ADULT GROWTH HORMONE
Please fill out form completely

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
RECIPIENT DOB:	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
Is prescribing physician board certified endocrinologist or gastroenterologist ? ☐ YES ☐ NO	PHONE:	FAX:

Part III: TO BE COMPLETED BY PHYSICIAN:

REQUESTED DRUG:	**Requested Dosage:** (must be completed)
☐ INITIAL REQUEST ☐ RENEWAL REQUEST	**Diagnosis for this request:**

QUALIFICATIONS FOR COVERAGE:

Does patient have a diagnosis of: ☐ Panhypopituitarism **OR** ☐ Prader-Willi Syndrome (If either, may skip questions 1, 2, & 3)

1. IGF-1 Level:

2. Provocative testing:

Type_____Results_____Date_____

Type_____Results_____Date_____

3. Has the patient been screened for intracranial malignancy or tumor? ☐ YES ☐ NO

4. Does the patient have any of the following contraindications? Check all that apply.
☐ Proliferative Diabetic retinopathy ☐ Benign intracranial hypertension ☐ NONE

Physician signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE:	FAX:
DRUG NAME:	NDC#:

PRIOR AUTHORIZATION REQUEST FORM
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

PEDIATRIC GROWTH HORMONE

Please fill out form completely (Note: if this is a renewal request, please include height chart and documentation regarding efficacy with the request)

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
RECIPIENT DOB:	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
Is prescribing physician board certified endocrinologist or nephrologist? ☐ YES ☐ NO	PHONE:	FAX:

Part III: TO BE COMPLETED BY PHYSICIAN:

REQUESTED DRUG:	**Requested Dosage:** (must be completed)
☐ INITIAL REQUEST ☐ RENEWAL REQUEST	**Diagnosis for this request:**

QUALIFICATIONS FOR COVERAGE:
(Renewal requests do NOT need to answer the questions below, please submit height chart and documentation of efficacy):

For Growth Hormone Deficiency (please submit either IGF-1 level OR provocative testing results):

IGF-1 Level:_____

Provocative testing: Type_____Results_____Date_____

Has the patient been screened for intracranial malignancy or tumor? ☐ YES ☐ NO

For GHD AND Chronic Renal Insufficiency:
Is the patient's height value or growth velocity less than 2 standard deviations below the mean for age and/or Tanner Stage?
☐ YES ☐ NO

For Idiopathic Short Stature and SGA:
Please indicate patients height or include chart documentation:

Please indicate patient's predicted height:

For All Patients:
Does the patient have any of the following contraindications? Check all that apply.

☐ Benign intracranial hypertension ☐ Closed epiphyses ☐ NONE

Physician signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE:	FAX:
DRUG NAME:	NDC#:

HEAD LICE MEDICATION PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a prescription for lindane or malathion must use Rid® or Nix® first line.

- **Rid or Nix may be prescribed WITHOUT a prior authorization**
- **For a trial to be considered a failure, patients must use Rid or Nix as directed, including retreatment within 7-10 days after the first treatment.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of Rid or Nix in the last 30 days.	Did trial include retreatment within 7-10 days after the first treatment? ❑ YES ❑ NO
Adverse Reaction (attach FDA MedWatch form) or contraindication: (provide description below):	
Medical Justification for use of lindane or malathion without trial of Nix:	
Physician Signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

MAXIMUM UNITS OVERRIDE REQUEST
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

- **SD Medicaid requires that patients exceeding the maximum recommended quantity/month submit an override request and provide medical justification for exceeding the maximum units.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy)

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy)

PHYSICIAN NAME:		PHYSICIAN MEDICAID ID NUMBER:
City:	FAX: ( )	Phone: ( )

Part III: TO BE COMPLETED BY PHYSICIAN

REQUESTED BRAND NAME DRUG:	**Requested Dosage:** (must be completed)
	Diagnosis for this request:

Qualifications for coverage:

Medical Justification (please include previous and current dosage):

Physician Signature: Date:

Part IV: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

MOXATAG PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients have a trial of amoxicillin before receiving a PA for Moxatag.

- **Amoxicillin does not require a PA**
- **Patient must fail therapy on generic amoxicillin before a PA will be considered.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Medication Requested: □ **MOXATAG**	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

❑ Failed amoxicillin	Start Date:	Dose:
	End Date:	Frequency:

Adverse Reaction (attach FDA MedWatch form) or contraindication to inactive ingredients in amoxicillin: (provide description below):

Medical Justification for use of Moxatag without trial of amoxicillin:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

NUCYNTA
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Nucynta must try an immediate release schedule-II opioid as first line therapy.

- **Nucynta should only be used as a second line agent for opioid naïve patients following failure with other immediate release schedule-II opioids.**
- **Immediate release oxycodone, oxymorphone, hydromorphone, and meperidine do not require a prior authorization.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:			Diagnosis for this request:	
□ Failed Therapy	Dose	Frequency	Start Date	End Date
PHYSICIAN SIGNATURE:				DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date:	/	/		Initials: _____	
Approved - Effective dates of PA:	From:	/	/	To:	/ /
Denied: (Reasons)					

NUVIGIL and PROVIGIL
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Nuvigil or Provigil must submit a prior authorization form.

- **Prior authorization will be granted if the requested product has been approved by the FDA for the indication listed.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:	**FDA approved indication for this request:**
□ **Nuvigil** _____	□ **Narcolepsy**
□ **Provigil**_____	□ **Excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome**
	□ **Shift work sleep disorder**

PHYSICIAN SIGNATURE:	DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

PROTON PUMP INHIBITOR PRIOR AUTHORIZATION

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving proton pump inhibitors use **Prilosec OTC, omeprazole 20mg or lansoprazole** first line.

- **Prilosec OTC, omeprazole 20mg, or lansoprazole may be prescribed WITHOUT prior authorization.**
- **Prior authorization is NOT required for patients < 13 years of age**
- **Patients must use Prilosec, omeprazole 20mg, or lansoprazole for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute treatment failure.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy)

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy)

PHYSICIAN NAME:	PHYSICIAN DEA NUMBER:	
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN

REQUESTED DRUG:

- ❑ ACIPHEX
- ❑ NEXIUM
- ❑ PREVACID
- ❑ PANTOPRAZOLE
- ❑ PREVPAC
- ❑ PRILOSEC RX
- ❑ PROTONIX
- ❑ ZEGERID
- ❑ KAPIDEX

Requested Dosage: (must be completed)

Diagnosis:

- ❑ GERD
- ❑ Erosive esophagitis
- ❑ H. pylori
- ❑ Barrett's esophagitis
- ❑ Hypersecretory conditions
- ❑ Peptic ulcer
- ❑ Duodenal ulcer

Qualifications for coverage:

- ❑ Failed Prilosec OTC, omeprazole 20mg, or lansoprazole

Was Prilosec OTC/omeprazole/lansoprazole trial for at least 14 days?
❑ YES ❑ NO

Dose:

Frequency:

- ❑ Adverse Reaction to Prilosec OTC/Omeprazole/Lansoprazole (attach FDA Medwatch form) or contraindicated (provide description below):

- ❑ Inability to take or tolerate oral tablets (must check a box below):
  - ❑ Tube Fed
  - ❑ Requires soft food or liquid administration

  Other (provide description at right)

Physician Signature:	Date:

Part IV: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE:	FAX:

Part V: FOR OFFICIAL USE ONLY

NDC#:

Date: / /

Approved -
Effective dates of PA: From: / / Initials: _____

Denied (Reasons): To: / /

SANCUSO
PRIOR AUTHORIZATION

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Sancuso must be unable to tolerate oral medications.

- **Patients must be unable to tolerate oral therapy for chemotherapy-induced nausea and vomiting.**
- **Patients able to tolerate oral medications must use a generic 5-hydroxytryptamine-3 receptor antagonist or other anti-nausea medication for at least 14 days for the trial to be considered a failure.**
- **Patients must be receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:	Patient able to tolerate oral medications that have failed on other medications:
□ Sancuso _____	Failed medication (name and dosage)_____
□ Patient unable to tolerate oral medications	Was trial for at least 14 days? □ YES □ NO
PHYSICIAN SIGNATURE:	DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

ORACEA and SOLODYN
PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Oracea or Solodyn must try a first line agent.

- **Doxycycline, minocycline, and tetracycline do not require a prior authorization.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:		Diagnosis for this request:	
□ Failed Therapy Dose	Frequency	Start Date	End Date
PHYSICIAN SIGNATURE:			DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

TARGETED IMMUNE MODULATORS
PRIOR AUTHORIZATION

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Orencia, Humira, Enbrel, Amevive, Kineret, Cimzia, Remicade, and Simponi must submit a prior authorization form.

- **Prior authorization will be granted if the requested product has been approved by the FDA for the indication listed.**
- **Physician administered medications do not require a prior authorization**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:	**FDA approved indication for this request:**
□ **Orencia** _____	□ **Adult Rheumatoid Arthritis**
□ **Amevive** _____	□ **Juvenile Idiopathic Arthritis**
□ **Enbrel** _____	□ **Plaque Psoriasis**
□ **Kineret** _____	□ **Ankylosing Spondylitis**
□ **Humira** _____	□ **Psoriatic Arthritis**
□ **Cimzia** _____	□ **Crohn's Disease**
□ **Remicade** _____	□ **Ulcerative Colitis**
□ **Simponi** _____	

PHYSICIAN SIGNATURE: DATE:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date:	/	/	Initials: _____		
Approved - Effective dates of PA:	From: /	/	To:	/	/
Denied: (Reasons)					

ULORIC
PRIOR AUTHORIZATION

SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Uloric must try allopurinol as first line therapy or have documented renal/hepatic dysfunction.

- **Allopurinol does not require a prior authorization.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	MEDICAID ID NUMBER:	RECIPIENT DATE OF BIRTH

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage:		Diagnosis for this request:	
□ Failed Allopurinol Therapy	Dose	Frequency	Start Date / End Date
□ Renal or Hepatic Impairment	□ Other (please explain) _____		
PHYSICIAN SIGNATURE:		DATE:	

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
PHONE: ( ):	FAX:: ( )
DRUG:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

ULTRAM ER/RYZOLT PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients have a trial of tramadol before receiving a PA for Ultram ER or Ryzolt.

- **Patients must use generic tramadol for a minimum of 30 days for the trial to be considered a failure.**
- **Ultram ER and Ryzolt will have a quantity limit of 30 tablets per month.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN DEA NUMBER:
City:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Dosage: (must be completed)

Diagnosis for this request:

Qualifications for coverage:

❑ Patient is currently stable on Ultram ER/Ryzolt

❑ Failed trial of tramadol	Was tramadol trial for at least 30 days? ❑ YES ❑ NO	Tramadol Dose:
		Tramadol Frequency:

Adverse Reaction (attach FDA MedWatch form) or contraindication to tramadol: (provide description below):

Medical Justification for use of Ultram ER or Ryzolt without trial of tramadol:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

VUSION PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a prescription for Vusion must use nystatin or OTC miconazole first line.

- **Nystatin or miconazole OTC may be prescribed WITHOUT a prior authorization**
- **Patients must use nystatin or OTC miconazole for a minimum of 14 days for the trial to be considered a failure.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**
Qualifications for coverage:	
❑ Failed trial of nystatin or OTC miconazole in the last 30 days	Was trial for at least 14 days? ❑ YES ❑ NO
Adverse Reaction (attach FDA Medwatch form) or contraindication: (provide description below):	
Medical Justification for use of Vusion without trial of miconazole or nystatin:	
Physician Signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

XOLAIR PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a prescription for Xolair must have moderate to severe persistent asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms inadequately controlled with inhaled corticosteroids.

- **Xolair will be covered for patients with a diagnosis of moderate to severe persistent asthma who have elevated serum levels of IgE.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:			PHYSICIAN PROVIDER NUMBER:
City:	State:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug and Dosage: (must be completed)	**Diagnosis for this request:**

Qualifications for coverage:

- ❑ IgE level (Give date of test and results)

_____

Adverse Reaction (attach FDA Medwatch form) or contraindication: (provide description below):

Medical Justification for use of Xolair without trial of inhaled corticosteroids:

Physician Signature: Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAID PROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2010 – July 31, 2010

Time Ratio

Total PAs	Response Under 8 Hours	Response Over 8 Hours	% Under 8 Hours	% Over 8 Hours
1,898	1,893	5	99.74%	0.26%

By Form Type

Form Type	Description	Approve	Deny
AFX	Amrix and Fexmid	0	3
ALT	Altabax	1	9
AMB	Ambien CR	8	3
ANF	Anti-Infectives	1	8
ANT	Antihistamines	67	179
ARB	ARBS	22	20
DAW	Dispense As Written	27	21
GRH	Growth Hormone	2	0
HLM	Head Lice Medication	31	46
MAX	Max Units Override	76	1,104
NUC	Nucynta	4	16
PPI	Proton Pump Inhibitors	64	132
SMR	Skeletal Muscle Relaxants	0	2
STI	Stimulants	2	19
TIM	Targeted Immunomodulators	2	0
ULT	Ultram ER	3	18
VUS	Vusion	0	7
XEN	Xenical	1	3
Totals		311	1,587

By Request Type

07/01/10 – 07/31/10	# of	Electronic Requests		Faxed Requests	
	Requests	#	%	#	%
Amrix and Fexmid	3	3	100%	0	0%
Altabax	10	9	90%	1	10%
Ambien CR	11	10	91%	1	9%
Anti-infectives	9	8	89%	1	11%
Antihistamines	246	193	78%	53	22%
ARBS	42	32	76%	10	24%
Dispense As Written	48	15	31%	33	69%
Growth Hormone	2	0	0%	2	100%
Head Lice Medication	77	41	53%	36	47%
Max Units Override	1,180	1,124	95%	56	5%
Nucynta	20	13	65%	7	35%
Proton Pump Inhibitors	196	159	81%	37	19%
Skeletal Muscle Relaxants	2	2	100%	0	0%
Stimulants	21	16	76%	5	24%

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2010 – July 31, 2010

07/01/10 – 07/31/10	# of	Electronic Requests		Faxed Requests	
	Requests	#	%	#	%
Targeted Immunomodulators	2	0	0%	2	100%
Ultram ER	21	18	86%	1	14%
Vusion	7	6	86%	1	14%
Xenical	1	0	0%	1	100%
Prior Authorization Totals	1,898	1,649	87%	249	13%

Electronic PAs (unique)

07/01/10 - 07/31/10	# Unique Approved	# Unique Denied	# Unique Incomplete	Unique Total	Approval %	Total Transactions
Prior Authorizations:						
Amrix and Fexmid	0	3	0	3	0.00%	3
Altabax	0	9	0	9	0.00%	9
Ambien CR	7	3	0	10	70.00%	10
Anti-infectives	0	8	0	8	0.00%	8
Antihistamines	24	162	0	186	12.90%	192
ARBS	12	20	0	32	37.50%	32
Dispense As Written	0	15	0	15	0.00%	15
Head Lice Medication	0	40	0	40	0.00%	41
Max Units Override	33	1,008	0	1,041	3.20%	1,125
Nucynta	0	13	0	13	0.00%	13
Proton Pump Inhibitors	35	117	0	152	23.00%	159
Skeletal Muscle Relaxants	0	2	0	2	0.00%	2
Stimulants	0	16	0	16	0.00%	16
Ultram ER	1	17	0	18	5.60%	18
Vusion	0	5	0	5	0.00%	6
Prior Authorization Totals:	112	1,438	0	1,550	7.20%	1,649

Manual PAs (unique)

07/01/10 - 07/31/10	# Requests	# Approved	% Approved	# Denied	% Denied
Prior Authorizations:					
Altabax	1	1	100%	0	0%
Ambien CR	1	1	100%	0	0%
Anti-Infectives(anti-biotic)	1	1	100%	0	0%
Antihistamines	53	43	81%	10	19%
ARBS	10	10	100%	0	0%
Dispense As Written	33	27	82%	6	18%
Growth Hormone	2	2	100%	0	0%
Head Lice Medication	36	31	86%	5	14%
Max Units Override	56	43	77%	13	23%

HEALTH INFORMATION DESIGNS

South Dakota Medicaid
Monthly Prior Authorization Report
July 1, 2010 – July 31, 2010

07/01/10 - 07/31/10	# Requests	# Approved	% Approved	# Denied	% Denied
Nucynta	7	4	57%	3	43%
Proton Pump Inhibitors	37	29	78%	8	22%
Stimulants	5	2	40%	3	60%
Targeted Immune Modulators	2	2	100%	0	0%
Ultram ER	3	2	67%	1	33%
Vusion	1	0	0%	1	100%
Xenical	1	1	100%	0	0%
Prior Authorization Totals	249	199	80%	50	20%

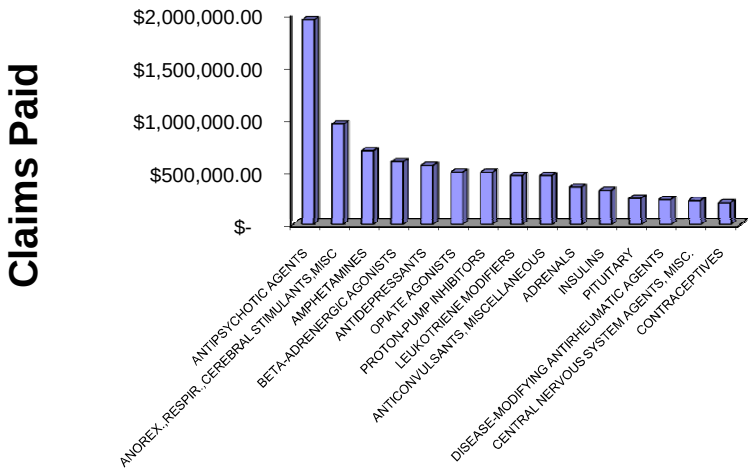
SOUTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2010 - 06/30/2010

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	7,247	$ 1,943,260.84	$ 268.15	3.47%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	6,314	$ 952,845.52	$ 150.91	3.02%
AMPHETAMINES	4,812	$ 699,121.28	$ 145.29	2.30%
BETA-ADRENERGIC AGONISTS	8,400	$ 594,750.87	$ 70.80	4.02%
ANTIDEPRESSANTS	15,069	$ 559,508.81	$ 37.13	7.21%
OPIATE AGONISTS	14,538	$ 495,223.51	$ 34.06	6.95%
PROTON-PUMP INHIBITORS	6,176	$ 493,524.49	$ 79.91	2.95%
LEUKOTRIENE MODIFIERS	3,916	$ 465,198.10	$ 118.79	1.87%
ANTICONVULSANTS, MISCELLANEOUS	7,363	$ 464,882.12	$ 63.14	3.52%
ADRENALS	5,444	$ 353,739.05	$ 64.98	2.60%
INSULINS	1,874	$ 322,705.47	$ 172.20	0.90%
PITUITARY	613	$ 246,933.50	$ 402.83	0.29%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	154	$ 235,922.96	$ 1,531.97	0.07%
CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,246	$ 226,255.63	$ 181.59	0.60%
CONTRACEPTIVES	3,593	$ 205,545.75	$ 57.21	1.72%
TOTAL TOP 15	86,759	$ 8,259,417.90	$ 95.20	41.49%

Total Rx Claims From 04/01/2010 - 06/30/2010	209,114

Top 15 Therapeutic Classes
Based on Total Cost of Claims

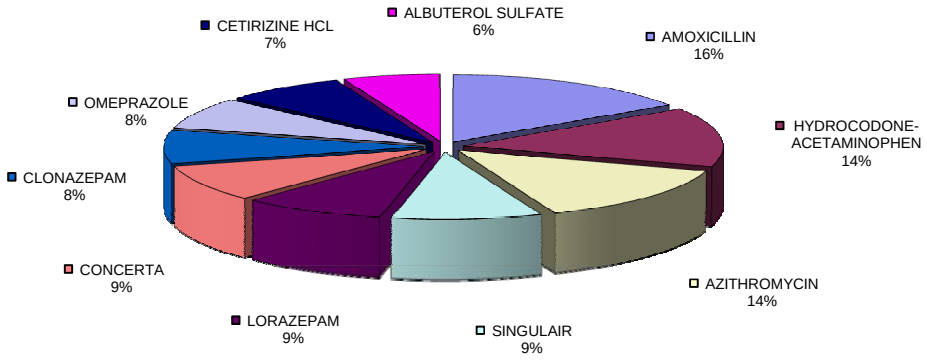


TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2010 - 06/30/2010

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	6,501	$ 65,303.68	$ 10.05	3.11%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	5,913	$ 63,721.44	$ 10.78	2.83%
AZITHROMYCIN	MACROLIDES	5,827	$ 117,957.29	$ 20.24	2.79%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,903	$ 463,757.94	$ 118.82	1.87%
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	3,710	$ 32,739.20	$ 8.82	1.77%
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	3,618	$ 612,034.54	$ 169.16	1.73%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,289	$ 29,062.14	$ 8.84	1.57%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	3,135	$ 58,188.78	$ 18.56	1.50%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	3,112	$ 62,981.35	$ 20.24	1.49%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	2,500	$ 45,457.14	$ 18.18	1.20%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,371	$ 21,009.47	$ 8.86	1.13%
AMOX TR-POTASSIUM CLAVULANA	PENICILLINS	2,363	$ 67,805.19	$ 28.69	1.13%
SERTRALINE HCL	ANTIDEPRESSANTS	2,331	$ 20,961.42	$ 8.99	1.11%
LORATADINE	SECOND GENERATION ANTIHISTAMINES	2,286	$ 18,072.04	$ 7.91	1.09%
SULFAMETHOXAZOLE-TRIMETHOP	SULFONAMIDES (SYSTEMIC)	2,202	$ 19,345.20	$ 8.79	1.05%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,176	$ 19,648.90	$ 9.03	1.04%
CEFDINIR	CEPHALOSPORINS	2,131	$ 97,622.99	$ 45.81	1.02%
CEPHALEXIN	CEPHALOSPORINS	2,068	$ 25,727.51	$ 12.44	0.99%
DEXTROAMPHETAMINE-AMPHETAI	AMPHETAMINES	2,011	$ 357,010.46	$ 177.53	0.96%
TRAMADOL HCL	OPIATE AGONISTS	1,977	$ 29,036.50	$ 14.69	0.95%
TRAZODONE HCL	ANTIDEPRESSANTS	1,899	$ 13,161.92	$ 6.93	0.91%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,889	$ 44,012.67	$ 23.30	0.90%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITOR	1,844	$ 12,557.52	$ 6.81	0.88%
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	1,735	$ 11,312.07	$ 6.52	0.83%
VYVANSE	AMPHETAMINES	1,732	$ 225,640.51	$ 130.28	0.83%
TOTAL TOP 25		72,523	$ 2,534,127.87	$ 34.94	34.68%

Total Rx Claims From 04/01/2010 - 06/30/2010	209,114

Top 10 Drugs
Based on Number of Claims

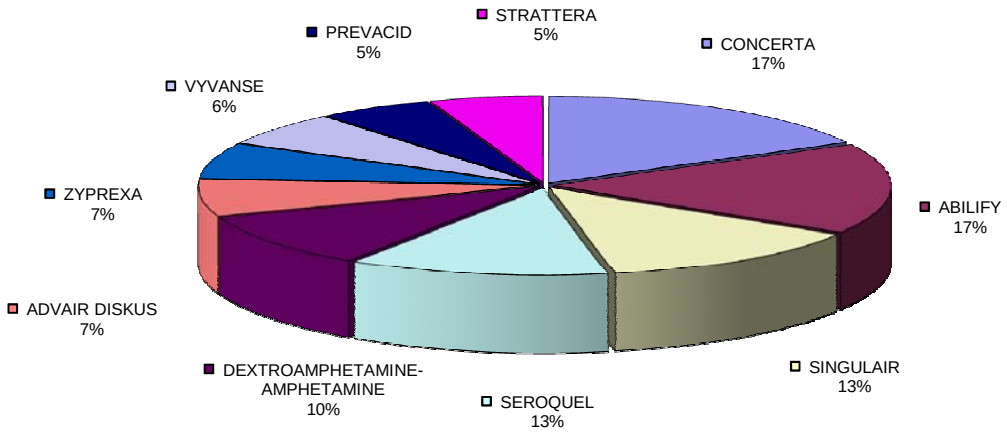


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2010 - 06/30/2010

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
CONCERTA	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	3,618	$ 612,034.54	$ 169.16	1.73%
ABILIFY	ANTIPSYCHOTIC AGENTS	1,469	$ 592,884.74	$ 403.60	0.70%
SINGULAIR	LEUKOTRIENE MODIFIERS	3,903	$ 463,757.94	$ 118.82	1.87%
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,511	$ 445,589.54	$ 294.90	0.72%
DEXTROAMPHETAMINE-AMP	AMPHETAMINES	2,011	$ 357,010.46	$ 177.53	0.96%
ADVAIR DISKUS	BETA-ADRENERGIC AGONISTS	1,183	$ 238,392.82	$ 201.52	0.57%
ZYPREXA	ANTIPSYCHOTIC AGENTS	409	$ 234,818.66	$ 574.13	0.20%
VYVANSE	AMPHETAMINES	1,732	$ 225,640.51	$ 130.28	0.83%
PREVACID	PROTON-PUMP INHIBITORS	1,097	$ 195,071.77	$ 177.82	0.52%
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,197	$ 193,004.71	$ 161.24	0.57%
FOCALIN XR	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,107	$ 167,914.91	$ 151.68	0.53%
OXYCONTIN	OPIATE AGONISTS	450	$ 165,508.93	$ 367.80	0.22%
SEROQUEL XR	ANTIPSYCHOTIC AGENTS	417	$ 137,872.28	$ 330.63	0.20%
CYMBALTA	ANTIDEPRESSANTS	874	$ 135,216.28	$ 154.71	0.42%
GEODON	ANTIPSYCHOTIC AGENTS	337	$ 133,210.31	$ 395.28	0.16%
FLOVENT HFA	ADRENALS	1,022	$ 123,743.24	$ 121.08	0.49%
AZITHROMYCIN	MACROLIDES	5,827	$ 117,957.29	$ 20.24	2.79%
LEXAPRO	ANTIDEPRESSANTS	1,147	$ 110,332.31	$ 96.19	0.55%
NEXIUM	PROTON-PUMP INHIBITORS	539	$ 109,166.66	$ 202.54	0.26%
PULMOZYME	ENZYMES	52	$ 107,489.03	$ 2,067.10	0.02%
RISPERDAL CONSTA	ANTIPSYCHOTIC AGENTS	132	$ 107,286.10	$ 812.77	0.06%
HUMIRA	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	57	$ 104,540.30	$ 1,834.04	0.03%
ONE TOUCH ULTRA TEST ST	DIABETES MELLITUS	777	$ 102,710.17	$ 132.19	0.37%
NOVOLOG	INSULINS	516	$ 101,521.81	$ 196.75	0.25%
CEFDINIR	CEPHALOSPORINS	2,131	$ 97,622.99	$ 45.81	1.02%
TOTAL TOP 25		33,515	$ 5,380,298.30	$ 160.53	16.03%

Total Rx Claims From 04/01/2010 - 06/30/2010	209,114

Top 10 Drugs
Based on Total Claims Cost



Patent No.	Tradename of Approved Product	Original Exp. Date (Note 1)	Extension	Approval Date (If Relevant) (Note 2)	Extended Expiration Date
4,628,098	PREVACID	29-Jul-05	1,381 days	10-May-95	10-May-09
4,634,697	CEDAX	1-Oct-04	5 years		1-Oct-09
4,639,436	GLYSET	27-Jan-04	5 years		27-Jan-09
4,650,787	SANVAR	25-Apr-05	1 year (note 5)		25-Apr-09
4,650,884	CELEXA	2-Aug-05	5 years		2-Aug-10
4,668,669	SYNERCID	10-Jan-06	1,333 days		4-Sep-09
4,681,893	LIPITOR	30-May-06	1,213 days		24-Sep-09
4,687,777	ACTOS	18-Jan-06	5 years		18-Jan-11
4,689,338	ALDARA	25-Aug-04	5 years		25-Aug-09
4,689,339	ANTISEDAN	21-Nov-05	1,719 days	6-Aug-96	6-Aug-10
4,695,623	INFERGEN	22-Sep-04	5 years		22-Sep-09
4,696,949	FARESTON	29-Sep-04	5 years		29-Sep-09
4,703,063	FLOMAX	27-Oct-04	5 years		27-Oct-09
4,717,720	DIFFERIN	10-Apr-06	1,512 days	31-May-96	31-May-10
4,745,177	IPRIVASK	17-May-05	5 years		17-May-10
4,753,935	CELLCEPT	30-Jan-07	824 days	3-May-95	3-May-09
4,757,057	NORMIFLO	12-Jul-05	5 years		12-Jul-10
4,758,579	PROTONIX	19-Jul-05	5 years		19-Jul-10
4,761,237	EXTRANEAL	2-Aug-05	1468 days		9-Aug-09
4,762,710	CERTIVA	16-Jun-06	1,807 days		28-May-11
4,784,950	NOVOSEVEN	15-Nov-05	5 years		15-Nov-10
4,795,751	ZAGAM	28-Oct-06	1,195 days		4-Feb-10
4,798,827	SYNERCID	21-May-07	1,770 days		25-Mar-12
4,801,577	ANTAGON	5-Feb-07	5 years		5-Feb-12
4,808,605	POSICOR	10-Nov-07	1,130 days		14-Dec-10
4,808,614	GEMZAR	28-Feb-06	1,537 days*	15-May-96	15-May-10
4,808,616	AROMASIN	7-Jul-06	1,729 days		1-Apr-11
4,812,561	CEDAX	1-Jul-07	903 days*	20-Dec-95	20-Dec-09
4,814,470	TAXOTERE	14-Jul-07	1,035 days*	14-May-96	14-May-10
4,826,763	GLUCAGEN	2-May-06	1,421 days		23-Mar-10
4,826,868	ZUBRIN	29-May-06	1,404 days		2-Apr-10

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4,831,031	GEODON	2-Mar-07	5 years		2-Mar-12
4,839,342	OPTIMMUNE	2-Sep-07	700 days*	2-Aug-95	2-Aug-09
4,839,350	SPECTRACEF	13-Jun-06	1,036 days		14-Apr-09
4,840,896	OVIDREL	20-Jun-06	1,044 days		29-Apr-09
4,844,882	ALBUNEX	29-Dec-07	220 days*	5-Aug-94	5-Aug-08
4,845,075	Concentrate	4-Jul-06	1,578 days		29-Oct-10
4,847,265	PLAVIX	12-Feb-08	1,374 days		17-Nov-11
4,855,290	EVOXAC	8-Aug-06	1,118 days		30-Aug-09
4,859,692	ACCOLATE	22-Aug-06	1,496 days*	26-Sep-96	26-Sep-10
4,863,908	MONUROL	23-Feb-05	1,527 days		30-Apr-09
4,868,112	REFACTO	19-Sep-06	1,258 days		28-Feb-10
4,870,086	NAROPIN	24-Nov-06	1,400 days*	24-Sep-96	24-Sep-10
4,873,259	ZYFLO	10-Feb-07	1,398 days*	9-Dec-96	9-Dec-10
4,874,794	ABREVA	28-Apr-09	5 years		28-Apr-14
4,876,248	SKELID	24-Oct-06	1,194 days		30-Jan-10
4,879,288	SEROQUEL	20-Mar-07	1,651 days*	26-Sep-97	26-Sep-11
4,885,243	CUBICIN	5-Dec-06	1,348 days		14-Aug-10
4,886,812	MIRAPEX	12-Dec-06	1,564 days		25-Mar-11
4,895,841	ARICEPT	20-Jun-08	888 days*	25-Nov-96	25-Nov-10
4,897,255	VERLUMA	30-Jan-07	1,298 days*	20-Aug-96	20-Aug-10
4,898,724	QUADRAMET	6-Feb-07	1,511 days	28-Mar-97	28-Mar-11
4,900,735	ZILMAX	11-Dec-07	5 years		11-Dec-12
4,904,769	PRECOSE	27-Feb-07	922 days*	6-Sep-95	6-Sep-09
4,906,755	ANZEMET	6-Mar-07	1,579 days		2-Jul-11
4,910,214	PRECEDEX	15-Jul-08	5 years		15-Jul-13
4,911,932	VUSION	27-Mar-07	1 year (note 3)		27-Mar-09
4,927,814	BONIVA	9-Jul-07	1,713 days		17-Mar-12
4,927,855	NUVIGIL	22-May-07	1 year (note 3)		22-May-09
4,933,456	TESLASCAN	12-Jun-07	1,628 days*	26-Nov-97	26-Nov-11
4,935,437	ARIMIDEX	10-Jun-08	565 days	27-Dec-95	27-Dec-09
4,935,507	OMNICEF	8-Aug-08	1,213 days*	4-Dec-97	4-Dec-11

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4,937,078	SURPASS	26-Aug-08	1,748 days		9-Jun-13
4,937,234	NEUTERSOL	10-Aug-08	5 years		10-Aug-13
4,939,130	ZOMETA	13-Nov-07	1,755 days		2-Sep-12
4,943,569	MERREM	24-Jul-07	1,063 days*	21-Jun-96	21-Jun-10
4,947,840	INTEGRA	21-Aug-07	923 days*	1-Mar-96	1-Mar-10
4,948,807	EXELON	14-Aug-07	5 years		14-Aug-12
4,949,718	THERMA CHOICE	9-Sep-08	605 days		7-May-10
4,954,348	OXILAN	4-Sep-07	839 days	21-Nov-95	21-Dec-09
4,957,924	VALTREX	4-Aug-08	323 days*	23-Jun-95	23-Jun-09
4,959,366	TIKOSYN	25-Sep-07	5 years		25-Sep-12
4,963,489	DERMAGRAFT	16-Oct-07	5 years		16-Oct-12
4,966,891	XELODA	8-Nov-08	796 days		13-Jan-11
4,978,672	FEMARA	18-Dec-07	1,263 days		3-Jun-11
4,980,470	TEQUIN	25-Dec-07	721 days		15-Dec-09
4,990,517	AVELOX	30-Jun-09	901 days		18-Dec-11
4,996,335	LOTEMAX and ALREX	26-Feb-08	1,473 days*	9-Mar-98	9-Mar-12
4,997,841	AMERGE	12-Aug-08	694 days		7-Jul-10
5,002,953	AVANDIA	30-Aug-08	1,113 days		17-Sep-11
5,004,758	HYCAMTIN	2-Apr-08	786 days*	28-May-96	28-May-10
5,006,528	ABILIFY	20-Oct-09	5 years		20-Oct-14
5,006,530	BAYCOL	17-Jan-09	890 days*	26-Jun-97	26-Jun-11
5,008,256	TRITEC	17-Jul-09	387 days*	8-Aug-96	8-Aug-10
5,010,090	GABITRIL	23-Apr-08	1,255 days*	30-Sep-97	30-Sep-11
5,019,583	ULTIVA	15-Feb-09	512 days*	12-Jul-96	12-Jul-10
5,021,458	MENTAX	4-Jun-08	866 days*	18-Oct-96	18-Oct-10
5,023,269	CYMBALTA	11-Jun-08	5 years		11-Jun-13
5,034,230	ALAMAST	23-Dec-08	740 days		2-Jan-11
5,034,394	ZIAGEN	26-Jun-09	905 days		18-Dec-11
5,045,302	MYOVIEW	6-Oct-08	491 days*	9-Feb-96	9-Feb-10
5,045,552	ACIPHEX	3-Sep-08	1,708 days		8-May-13
5,047,407	EPIVIR	8-Feb-09	282 days*	17-Nov-95	17-Nov-09

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5,053,407	LEVAQUIN	1-Oct-08	810 days*	20-Dec-96	20-Dec-10
5,070,877	ADENOSCAN	10-Dec-08	159 days*	18-May-95	18-May-09
5,075,222	KINERET	24-Dec-08	5 years		24-Dec-13
5,075,445	DENAVIR	24-Dec-08	639 days*	24-Sep-96	24-Sep-10
5,079,262	LEVULIN KERASTICK	28-Jul-09	1,525 days		30-Sep-13
5,089,480	DECTOMAX	18-Feb-09	527 days*	30-Jul-96	30-Jul-10
5,089,509	TAZORAC	18-Feb-09	845 days*	13-Jun-97	13-Jun-11
5,095,030	VISUDYNE	24-Apr-07	1,599 days		9-Sep-11
5,096,890	ENABLEX	13-Mar-10	5 years		13-Mar-15
5,100,899	RAPAMUNE	6-Jun-09	1,492 days		7-Jul-13
5,101,013	LANTUS	31-Mar-09	977 days		3-Dec-11
5,114,923	NATRECOR	19-May-09	5 years		19-May-14
5,116,863	PATANOL	26-May-09	571 days*	18-Dec-96	18-Dec-10
5,135,943	ERTACZO	4-Aug-09	1,761 days		31-May-14
5,142,051	VISTIDE	25-Aug-09	305 days*	26-Jun-96	26-Jun-10
5,143,724	SYNVISC	9-Jul-10	395 days*	8-Aug-97	8-Aug-11
5,145,863	PHOTOFRIN	12-Jun-07	916 days		14-Dec-09
5,153,222	REMODULIN	6-Oct-09	5 years		6-Oct-14
5,155,268	CORVERT	13-Oct-09	76 days*	28-Dec-95	28-Dec-09
5,156,957	GONAL-F	8-May-07	1,605 days*	29-Sep-97	29-Sep-11
5,162,504	PROSTASCINT	10-Nov-09	352 days*	28-Oct-96	28-Oct-10
5,164,194	ASTELIN	17-Nov-09	349 days*	1-Nov-96	1-Nov-10
5,164,402	TROVAN	17-Nov-09	761 days*	18-Dec-97	18-Dec-11
5,171,569	BENEFIX	15-Dec-09	423 days*	11-Feb-97	11-Feb-11
5,180,668	REFLUDAN	19-Jan-10	777 days		6-Mar-12
5,192,808	ANIPRYL	31-Aug-10	272 days*	30-May-97	30-May-11
5,194,247	SOLAGE	16-Mar-10	1,365 days	10-Dec-99	10-Dec-13
5,196,444	ATACAND	18-Apr-11	413 days*	4-Jun-98	
5,198,533	CETROTIDE	17-Jul-07	1,195 days		24-Oct-10
5,202,333	ALOXI	13-Apr-10	5 years		13-Apr-15
5,206,244	BARACLUDE	18-Oct-10	1,587 days		21-Feb-15

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5,214,052	ACOVA	25-May-10	1,497 days		30-Jun-14
5,215,895	NEUMEGA	1-Jun-10	542 days*	25-Nov-97	25-Nov-11
5,221,763	RESCULA	22-Jun-10	754 days		15-Jul-12
5,223,256	RETAVASE	29-Jun-10	124 days*	30-Oct-96	30-Oct-10
5,234,404	GENESA	10-Aug-10	398 days*	12-Sep-97	12-Sep-11
5,236,952	TASMAR	17-Aug-10	530 days	29-Jan-98	29-Jan-12
5,246,925	ZEMPAR	21-Sep-10	574 days*	17-Apr-98	17-Apr-12
5,250,534	VIAGRA	18-Jun-11	283 days*	27-Mar-98	27-Mar-12
5,260,291	TEMODAR	9-Nov-10	1,006 days*	11-Aug-99	11-Aug-13
5,270,317	AVAPRO	20-Mar-11	194 days*	30-Sep-98	30-Sep-11
5,275,813	FEL-O-VAX	4-Jan-11	5 years		4-Jan-16
5,284,858	AMITIZA	8-Feb-11	1,252 days		14-Jul-14
5,292,740	TRACLEER	9-Jun-12	1,259 days	20-Nov-01	20-Nov-15
5,292,756	AGGRASTAT	8-Mar-11	433 days*	14-May-98	14-May-12
5,298,520	MAXALT	28-Jan-12	153 days*	29-Jun-98	29-Jun-12
5,344,932	ALIMTA	6-Sep-11	1,783 days		24-Jul-16
5,356,804	FABRAZYME	18-Oct-11	1,440 days		27-Sep-15
5,360,800	LOTRONEX	2-Feb-10	1,076 days		13-Jan-13
5,360,817	RELENZA	1-Nov-11	633 days		26-Jul-13
5,362,755	XOPENEX	8-Nov-11	503 days*	25-Mar-99	25-Mar-13
5,364,842	PRIALT	30-Dec-11	5 years		30-Dec-16
5,368,840	LUMENHANCE	29-Nov-11	20 days*	19-Dec-97	19-Dec-11
5,378,703	AZOPT	9-Apr-10	723 days*	1-Apr-98	1-Apr-12
5,382,518	ELITEK	17-Jan-12	1,638 days*	12-Jul-02	12-Jul-16
5,382,600	DETROL	17-Jan-12	68 days	25-Mar-98	25-Mar-12
5,385,732	TNKASE	31-Jan-12	853 days*	2-Jun-00	2-Jun-14
5,418,226	RAPLON	14-Apr-13	126 days*		18-Aug-13
5,420,319	ELOXATIN	7-Apr-13	1,220 days*	9-Aug-02	9-Aug-16
5,424,286	BYETTA	24-May-13	1,287 days		1-Dec-16
5,441,745	DAUNOXOME	28-May-08	238 days		21-Jan-09
5,446,194	COMTAN	29-Sep-12	416 days		19-Nov-13

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5,464,864	FROVA	7-Nov-12	1,096 days*	8-Nov-01	8-Nov-15
5,478,820	INVANZ	2-Feb-13	1,022 days*	21-Nov-01	21-Nov-15
5,480,668	NEOTAME	7-Nov-12	973 days*	9-Jul-02	8-Jul-15
5,494,903	TYGACIL	13-Aug-12	1,335 days		9-Apr-16
5,510,353	ZELNORM	23-Apr-13	1,188 days*	24-Jul-02	24-Jul-16
5,514,650	CANCIDAS	16-Mar-13	681 days*	26-Jan-01	26-Jan-15
5,521,184	GLEEVEC	28-May-13	586 days		4-Jan-15
5,521,207	DERAMAXX	30-Nov-13	883 days		1-May-16
5,523,221	GYNECARE INTERGEL	2-Jul-13	867 days*	16-Nov-01	16-Nov-15
5,527,521	DEFINITY	5-Apr-11	1,419 days		22-Feb-15
5,545,644	RELPAX	13-Aug-13	1,231 days*	26-Dec-02	26-Dec-16
5,547,853	AMEVIVE	20-Aug-13	1,259 days*	30-Jan-03	30-Jan-17
5,563,146	CYPHER	28-Apr-12	557 days		6-Nov-13
5,565,447	AXERT	15-Oct-13	569 days	7-May-01	7-May-15
5,565,467	AVODART	15-Oct-13	766 days*	20-Nov-01	20-Nov-15
5,567,817	VFEND	22-Oct-13	945 days	24-May-02	24-May-16
5,565,473	SINGULAIR	30-Nov-10	430 days		3-Feb-12
5,616,599	BENICAR	1-Apr-14	755 days*	25-Apr-02	25-Apr-16
5,618,913	NOVOLOG	8-Apr-14	61 days*	7-Jun-00	7-Jun-14
5,635,485	KETEK	21-Apr-15	1,076 days*	1-Apr-04	1-Apr-18
5,635,517	REVLIMID	24-Jun-16	1,167 days		4-Oct-19
5,639,443	IMAGENT	17-Jun-14	714 days*	31-May-02	31-May-16
5,639,639	LUVERIS	20-Jun-06	5 years		20-Jun-11
5,656,667	OMACOR	12-Aug-14	1,476 days		27-Aug-18
5,658,590	STRATTERA	11-Jan-15	685 days*	26-Nov-02	26-Nov-16
5,661,136	CLOLAR	26-Aug-14	1,237 days		14-Jan-18
5,661,151	NOXAFIL	26-Aug-14	1,788 days		19-Jul-19
5,667,767	ONYX LES	27-Jul-15	1,269 days		16-Jan-19
5,667,787	DAPTACEL	16-Sep-14	606 days*	14-May-02	14-May-16
5,681,814	INCRELEX	28-Oct-14	1,056 days		18-Sep-17
5,681,818	IPLEX	28-Oct-14	1,656 days		11-May-19

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5,686,411	SYMLIN	11-Nov-14	1,586 days*	16-Mar-05	16-Mar-19
5,688,819	LUMIGAN	21-Sep-12	698 days		20-Aug-14
5,719,147	EMEND	29-Jun-12	1,022 days		17-Apr-15
5,723,606	VAPRISOL	3-Mar-15	1,748 days		15-Dec-19
5,747,498	TARCEVA	6-Jun-15	1,251 days		8-Nov-18
5,750,497	LEVEMIR	12-May-15	1,497 days*	16-Jun-05	16-Jun-19
5,770,599	IRESSA	26-Apr-16	374 days*	5-May-03	5-May-17
5,776,456	ZEVALIN	7-Jul-15	227 days*	19-Feb-02	19-Feb-16
5,776,944	FACTIVE	15-Jun-15	659 days*	4-Apr-03	4-Apr-17
5,780,454	VELCADE	28-Oct-14	918 days		3-May-17
5,820,870	GARDACIL	13-Oct-15	1,199 days		24-Jan-19
5,827,937	RESTAYLANE	17-Jul-15	879 days*	12-Dec-03	12-Dec-17
5,840,299	TYSABRI	25-Jan-14	1,188 days*		27-Apr-17
5,843,901	PLENAXIS	1-Dec-15	725 days*	25-Nov-03	25-Nov-17
5,849,535	SOMAVERT	21-Sep-15	551 days*	25-Mar-03	25-Mar-17
5,849,911	REYATAZ	9-Apr-17	72 days*	20-Jun-03	20-Jun-17
5,851,795	ORENCIA	1-Dec-15	1,413 days*	25-Nov-03	25-Nov-17
5,852,195	APTIVUS	22-Dec-15	1,278 days	22-Jun-05	22-Jun-19
5,859,006	CIALIS	12-Jan-16	679 days*	21-Nov-03	21-Nov-17
5,876,746	ORTHO-EVRA	7-Jun-15	166 days*	20-Nov-01	20-Nov-15
5,886,036	KALETRA	29-Dec-12	325 days		19-Nov-13
5,889,052	TRAVATAN	3-Aug-13	486 days		2-Dec-14
5,914,331	EMTRIVA	29-Sep-15	642 days		2-Jul-17
5,932,211	ELAPRASE	3-Aug-16	1,126 days		3-Sep-19
5,951,974	PEG-INTRON	10-Nov-13	435 days*	19-Jan-01	19-Jan-15
5,968,976	FOSRENOL	19-Mar-16	951 days*	26-Oct-04	26-Oct-18
5,981,576	PREVICOX	9-Oct-16	651 days*	21-Jul-04	21-Jul-18
6,001,876	LYRICA (NDA No. 21-723)	16-Jul-17	533 days*	30-Dec-04	30-Dec-18
6,017,927	VESICARE	27-Dec-15	1,058 days*	19-Nov-04	19-Nov-18
6,051,698	MACUGEN	17-Oct-12	944 days		19-May-15
6,083,953	VALCYTE	28-Jul-14	244 days*	29-Mar-01	29-Mar-15

Patent No.	Tradename of Approved Product	Original Exp. Date (Note 1)	Extension	Approval Date (If Relevant) (Note 2)	Extended Expiration Date
6,090,382	HUMIRA	9-Feb-16	326 days*	21-Dec-02	31-Dec-16
6,107,458	MYCAMINE	29-Sep-15	1,265 days*	16-Mar-05	16-Mar-19
6,133,418	FUZEON	7-Jun-13	528 days		17-Nov-14
6,197,819	LYRICA (NDA No. 21-446)	6-Mar-18	300 days*	30-Dec-04	30-Dec-18
6,267,958	XOLAIR	14-Mar-16	463 days*	20-Jun-03	20-Jun-17
6,410,550	CHANTIX	13-Nov-18	544 days*	10-May-06	10-May-20
6,420,536	DRAXXIN	29-May-18	360 days*	24-May-05	24-May-19
6,465,504	EXJADE	24-Jun-17	650 days		5-Apr-19
6,596,746	SPRYCEL	13-Apr-20	76 days*		28-Jun-20

*	**Shows recalculated extension due to § 156(c)(3).**
**	**Previously granted extension under § 156 superceded by § 154 term.**
***	**Extension runs from the approval date, not the original expiration date. 35 U.S.C. § 156(d)(5)(E)(ii).**
Note 1	**The original expiration date assumes that all maintenance fees are paid and that there is no premature expiration of the patent.**
Note 2	**An approval date is normally only shown where the extension has been limited by the 14-year limit of 35 U.S.C. § 156(c)(3).**
Note 3	**Interim extension under 35 USC 156(e)(2).**
Note 4	**Terminal disclaimer filed after patent term extension was granted.**
Note 5	**Interim extension under 35 USC 156(d)(5).**

NOTE: This list is for informational purposes only and is not intended to have legal effect. Furthermore, this list does not include patents which have been extended only under § 156(e)(2) or § 156(d)(5) (patents which have only received an interim extension). Each patent number is hyperlinked to a copy of its certificate of extension, if available. A copy of the certificate of extension should be included in the "correction" section of the patent's images. See http://www.uspto.gov/patft/index.html to access the patent image database. Items shown in red are new relative to the last version of this web page. Accessed online August, 2010 at http://www.uspto.gov/patents/resources/terms/156.jsp.

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Anticipated Availability of First-Time Generics

(Update February 2010)

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Aceon (Solvay)	Perindopril Erbumine	Aurobindo, Ivax, Lupin, Roxane	Generic now available
Acular/Acular LS (Allergan)	Ketorolac Tromethamine Ophthalmic	Akorn, Alcon, Apotex, Sun LS: Akorn, Alcon, Apotex	Generic now available
Allegra D 12 HR (Sanofi-aventis)	Fexofenadine/Pseudoephedrine	Barr	Generic now available
Casodex (AstraZeneca)	Bicalutamide	Accord, Actavis Totowa, Kudco, Mylan, Sandoz, Sun, Synthon, Teva, Zydus	Generic now available
CellCept Roche	Mycophenolate Oral Capsule and Tablet	Accord, Apotex, Endo, Mylan, Roxane, Sandoz, Teva, Zydus	Generic now available
Depakote (Abbott)	Divalproex Sodium Delayed Release Tablet	Anchen, Dr. Reddy's, Lupin, Mylan, Nu Pharm, Orchid, Sandoz, Sun, Teva, Upsher Smith, Vintage, Wockhardt, Zydus	Generic now available
Depakote ER (Abbott)	Divalproex Extended-Release Tablet	Anchen, Impax, Mylan, Teva, Wockhardt, Zydus	Generic now available
Fosamax (Merck)	Alendronate	Apotex, Aurobindo, Austrapharma, Dr. Reddy's, Mylan, Sandoz, Sun, Teva, Watson	Generic now available

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Imitrex (GlaxoSmithKline)	Sumatriptan	Tablet: Aurobindo, Cobalt, Dr. Reddy's, Mylan, Orchid, Ranbaxy, Roxane, Sandoz, Sun, Teva Injectable: App Pharms, Bedford, JHP, Par, Sandoz, Teva Parenteral, Wockhardt	Generic now available
Keppra (UCB)	Levetiracetam	Apotex, Aurobindo, Boca, Cobalt, Dr. Reddy's, Invagen, Lupin, Mylan, Orchid, Roxane, Sandoz, Solco, Taro, Teva, Torrent, Wockhardt, Zydus Oral solution: Actavis Mid Atlantic, Amneal, Aurobindo, Cypress, Roxane, Silarx, Taro, Tolmar	Generic now available.
Mirapex (Boehringer Ingelheim)	Pramipexole	Barr	Generic now available
Optivar (Meda)	Azelastin Ophthalmic	Apotex	Generic now available
Plan B (Duramed)	Levonorgestrel	Watson	Generic now available
Prevacid (TAP)	Lansoprazole Capsule	Matrix, Teva	Generic now available
Prograf (Astellas Pharma)	Tacrolimus Capsule	Sandoz	Generic now available
Pulmicort Respules (AstraZeneca)	Budesonide Suspension for Inhalation	Apotex, Teva	Generic now available
Razadyne/Razadyne ER (Janssen)	Galantamine	Actavis Elizabeth, Barr, Bejing Yabao, Dr. Reddy's, Mylan, Roxane, Sandoz, Teva Extended Release: Barr, Impax Solution: Roxane	Generic now available

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Risperdal (Ortho-McNeil-Janssen)	Risperidone	Tablet: Actavis Totowa, Apotex, Aurobindo, Cadista, Cobalt, Dr. Reddy's, Mylan, Pliva, Sandoz, Synthon, Teva, Torrent, Vintage, West Ward, Wockhardt, Zydus Oral solution: Apotex, Aurobindo, Dr. Reddy's, Roxane, Teva, Wockhardt ODT: Dr. Reddy's, Par, Sandoz, Zydus	Generic now available
Sonata (King Pharmaceuticals)	Zaleplon	Aurobindo, Cipla, Mylan, Orchid, Roxane, Teva, Unichem, Upsher Smith, West Ward	Generic now available
Starlix (Novartis)	Nateglinide	Dr. Reddy's, Par, Teva	Generic now available
Topamax (Ortho-McNeil-Janssen)	Topiramate	Tablet: Accord, Apotex, Aurobindo, Cipla, Cobalt, Glenmark, Invagen, Mylan, Pliva, Ranbaxy, Roxane, Sun, Teva, Torrent, Unichem, Upsher Smith, Zydus Capsule: Cobalt, Mylan, Sandoz, Teva, Zydus	Generic now available
Valtrex (GlaxoSmithKline)	Valacyclovir	Ranbaxy	Generic now available
Xopenex 1.25 mg/0.5 ml (Sepracor)	Levalbuterol Concentrated Inhalation Solution	Breath, Dey	Generic now available
Zerit (Bristol-Myers Squibb)	Stavudine	Capsule: Aurobindo, Hetero, Matrix Solution: Aurobindo, Cipla	Generic now available
Astelin (Meda)	Azelastine HCL	Apotex[f]	March 2010[19]
Flomax (Boehringer Ingelheim)	Tamsulosin	Impax, Lek, Mylan, Ranbaxy, Teva, Wockhardt, Zydus	March 2010[2]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Cozaar (Merck)	Losartan	Aurobindo, Lek, Roxane, Teva, Zydus	April 2010
Hyzaar (Merck)	Losartan/HCTZ	Apotex, Lek, Roxane, Zydus	April 2010
Combivir (GlaxoSmithKline)	Lamivudine/Zidovudine	Aurobindo, Cipla, Emcure, Hetero, Matrix, Macleods, Pharmacare, Strides, Teva	May 2010
Epivir (GlaxoSmithKline)	Lamivudine	Tablet: Alkem, Aurobindo Pharma, Invagen, Macleods, Matrix, Ranbaxy, Strides Arcolab Solution: Aurobindo, Cipla	May 2010[d]
Femhrt (Warner Chilcott)	Norethindrone/Ethinyl Estradiol	Barr[f]	May 2010[h,3]
Taxotere (Sanofi-aventis)	Docetaxel	Hospira	May 2010
Arimidex (AstraZeneca)	Anastrozole	Natco, Roxane, Sandoz, Stason, Synthon, Teva, Watson, Zydus	June 2010
Effexor XR (Wyeth)	Venlafaxine Extended-Release Capsule	Impax, Mylan	July 2010[4]
Aricept (Pfizer/Eisai)	Donepezil	Apotex, Aurobindo, Par, Ranbaxy, Roxane, Teva ODT: Mutual Pharm	November 2010
Gemzar (Lilly)	Gemcitabine	Atavis Totowa, App, Hospira, Pliva, Sun, Teva Parenteral, Watson	November 2010
Quixin (Santen)	Levofloxacin Ophthalmic	Akorn, Apotex, Hi Tech	December 2010
Actos (Takeda)	Pioglitazone	Alphapharm, Mylan, Teva, Watson	January 2011
Rythmol SR (Reliant)	Propafenone	Par[f]	January 2011[5]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Uroxatral (Sanofi-aventis)	Alfuzosin	Apotex, Aurobindo, Invagen, Mylan, Sun, Teva, Torrent, Wockhardt	January 2011[d]
Femara (Novartis)	Letrozole	Mylan, Roxane, Teva, Zydus	March 2011
Xalatan (Pfizer)	Latanoprost	Apotex, Par	March 2011
Aromasin (Pfizer)	Exemestane	Roxane	April 2011
Levaquin (Ortho-McNeil-Janssen)	Levofloxacin	Tablet: Dr. Reddy's, Ivax, Lupin, Mylan, Ranbaxy, Teva, Wockhardt, Zydus Injection: Apotex, Bedford, Hospira, Sicor	June 2011
Nasacort AQ (Sanofi-aventis)	Triamcinolone Acetonide Nasal Spray	Barr	June 2011- December 2013[6]
YAZ (Bayer)	Drospirenone/Ethinyl Estradiol	Barr	July 2011
Gabitril (Cephalon)	Tiagabine	Sun	September 2011[d]
Symbyax (Lilly)	Olanzapine/Fluoxetine	Teva	October 2011
Zyprexa (Lilly)	Olanzapine	Barr, Dr. Reddy's, Mylan, Roxane, Sandoz, Teva	October 2011[d]
Caduet (Pfizer)	Amlodipine/Atorvastatin	Ranbaxy[f]	November 2011[7]
Lipitor (Pfizer)	Atorvastatin	Ranbaxy[f]	November 2011[7]
Avalide (Bristol-Myers Squibb)	Irbesartan/Hydrochlorothiazide	Mylan, Sandoz, Teva	March 2012[d]
Avandamet (GlaxoSmithKline)	Metformin/Rosiglitazone	Teva	March 2012

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Avandaryl (GlaxoSmithKline)	Rosiglitazone/Glimepiride	Teva	March 2012
Avandia (GlaxoSmithKline)	Rosiglitazone	Dr. Reddy's, Hikma, Mylan, Roxane, Sandoz, Teva, Watson	March 2012
Avapro (Bristol Myers Squibb)	Irbesartan	Cipla, Sandoz, Teva	March 2012[d]
Boniva (Roche)	Ibandronate	Tablet: Cobalt, Mylan, Orchid Injectable: Teva Parenteral	March 2012
Geodon (Pfizer)	Ziprasidone	Dr. Reddy's, Lupin, Sandoz	March 2012
Lexapro (Forest)	Escitalopram	Tablet: Actavis Elizabeth, Alphapharm, Apotex, Aurobindo, Caraco, Dr. Reddy's, Invagen, Ivax, Kali Labs, Lupin, Mylan, Sandoz, Teva, Watson, Zydus Capsule: Alphapharm Solution: Aurobindo	March 2012
Revatio (Pfizer)	Sildenafil	Teva	March 2012[d]
Seroquel (AstraZeneca)	Quetiapine	Dr. Reddy's, Teva	March 2012
Lescol/Lescol XL (Novartis)	Fluvastatin/Fluvastatin Sodium Extended-Release	Mylan Extended-Release: Par	April 2012
Provigil (Cephalon)	Modafinil	Apotex, Barr, Caraco, Carlsbad, Mylan, Sandoz, Teva	April 2012[8]
Plavix (Sanofi-aventis)	Clopidogrel	Apotex, Mutual Pharma, Mylan, Roxane	May 2012[9]
Viramune (Boehringer Ingelheim)	Nevirapine	Aurobindo, Aurobindo Pharma (suspension), Cipla, Emcure, Hetero, Huahai US, Macleods, Matrix, Ranbaxy, Strides Arcolab	May 2012

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Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Ziagen (GlaxoSmithKline)	Abacavir	Tablet: Aurobindo, Cipla, Matrix Solution: Aurobindo	June 2012[d]
Clarinex (Schering)	Desloratadine	Glenmark, Orchid	July 2012[10]
Femcon Fe (Warner Chilcott)	Ethinyl Estradiol/Norethindrone	Teva[f]	July 2012[20]
Singulair (Merck)	Montelukast	Tablet: Mylan, Roxane, Teva Chewable: Mylan	August 2012[d]
Detrol (Pfizer)	Tolterodine	Ranbaxy	September 2012[d]
Diovan (Novartis)	Valsartan	Ivax, Ranbaxy	September 2012
Diovan HCT (Novartis)	Valsartan/HCTZ	Mylan	September 2012
Exforge (Novartis)	Amlodipine/Valsartan	Matrix	September 2012
Propecia (Merck)	Finasteride	Actavis Totowa, Dr. Reddy's, Teva, Watson	January 2013
Zometa/Reclast (Novartis)	Zoledronic Acid	Apotex, Bedford, Hospira, Pharmaforce, Sun, Teva Parenteral	March 2013[d]
OxyContin (Purdue Pharma)	Oxycodone Extended-Release Tablet	Endo, Impax, Mallinckrodt	April 2013
Aciphex (Eisai)	Rabeprazole	Mylan	May 2013[11]
Rilutek (Sanofi-aventis)	Riluzole	Impax	June 2013
Advicor (Abbott)	Lovastatin/Niacin	Barr[f]	September 2013[21]
Comtan (Orion)	Entacapone	Wockhardt	September 2013[22]

More. . .

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Niaspan (Abbott)	Niacin Extended-Release Tablet	Barr[f]	September 2013[21]
Atacand (AstraZeneca)	Candesartan	Lek	January 2014[d]
Loestrin 24 Fe (Warner Chilcott)	Ethinyl Estradiol/Norethindrone Acetate	Watson[f]	January 2014[20]
Micardis (Boehringer Ingelheim)	Telmisartan	Watson	January 2014
Exelon (Novartis)	Rivastigmine	Dr. Reddy's, Sun, Watson Solution: Ranbaxy	February 2014[d]
Temodar (Schering)	Temozolomide	Barr	February 2014[h,12]
Avelox (Bayer)	Moxifloxacin	Dr. Reddy's, Teva	March 2014[13]
Zetia Merck/Shering-Plough	Ezetimibe	Glenmark	March 2014
Nexium (AstraZeneca)	Esomeprazole	Ranbaxy	May 2014[14]
Actonel (Proctor & Gamble)	Risedronate	Teva	June 2014[d]
Sustiva (Bristol-Myers Squibb)	Efavirenz	Aurobindo, Cipla, Emcure, Hetero, Matrix, Strides	September 2014
Vigamox (Alcon)	Moxifloxacin Ophthalmic	Teva	September 2014[d]
Namenda (Forest)	Memantine Tablet	Amneal, Lupin, Orchid, Wockhardt	December 2014[15]
Tarka (Abbott)	Trandolapril/Verapamil ER	Glenmark	February 2015
Aggrenox (Boehringer Ingelheim)	Aspirin/Dipyridamole	Barr	July 2015[16]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Gleevec (Novartis)	Imatinib	Sun	July 2015
Valcyte (Roche)	Valganciclovir	Ranbaxy	September 2015[d]
Zegerid (Santarus)	Omeprazole/Sodium Bicarbonate	Par	July 2016[d,17]
Strattera (Lilly)	Atomoxetine	Aurobindo, Mylan, Sandoz, Sun, Teva, Zydus	May 2017[d,18]
Atripla (Gilead)	Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate	Matrix	Uncertain[e]
Axert (Ortho-McNeil-Janssen)	Almotriptan	Teva	Uncertain[e]
Benicar/Benicar HCT (Daiichi Sankyo)	Olmesartan/Olmesartan HCTZ	Olmesartan: Mylan, Sandoz Olmesartan HCTZ: Mylan	Uncertain[e]
DynaCirc (Reliant)	Isradipine	Actavis Totowa, Cobalt	Uncertain[e]
Emtriva (Gilead)	Emtricitabine	Aurobindo, Matrix	Uncertain[e]
Epzicom (GlaxoSmithKline)	Abacavir Sulfate/Lamivudine	Aurobindo, Matrix	Uncertain[e]
Evista (Lilly)	Raloxifene	Teva	Uncertain[e]
Kaletra (Abbott)	Lopinavir/Ritonavir	Aurobindo, Cipla, Matrix	Uncertain[e]
Maxalt/Maxalt-MLT (Merck)	Rizatriptan	Tablet: Teva ODT: Mylan	Uncertain[e]
Patanol (Alcon)	Olopatadine	Apotex, Sandoz	Uncertain[e]
Prandin (Novo Nordisk)	Repaglinide	Caraco	Uncertain[g]

Brand[a] (Manufacturer)	**Generic Name**	**Generic Manufacturer(s)[b,1]**	**Anticipated Availability[c]**
Skelaxin (King Pharmaceuticals)	Metaxalone	Corepharma	Uncertain[e]
Viread (Gilead)	Tenofovir Disproxil Fumarate	Aurobindo, Cipla, Matrix	Uncertain[e]
Zyvox (Pfizer)	Linezolid Tablet	Glenmark, Mylan, Teva	Uncertain[e]

a. This list is not all-inclusive.
b. Current as of February 2010. These are manufacturers with either approval or tentative approval to market the generic version of the drug unless otherwise noted. For drugs already available, only manufacturers with "approval" are listed.
c. Generic availability is subject to change as a result of litigations and patent exclusivities. Products are either approved or tentatively approved and waiting for patents to expire or resolution of litigation to gain final approval.
d. On-going litigation, availability may be sooner than patent expiration date.
e. Availability uncertain due to on-going litigation. Because there are multiple patent expiration dates and little information concerning which patents are being challenged, we are unable to estimate a date of availability at this time. We will continue to follow and update when new information is available.
f. Generic manufacturer has not received approval or tentative approval from the FDA, but has settled patent litigation with the brand manufacturer.
g. Patents have expired; however, generics are not yet available.
h. Generic manufacturer has received approval or tentative approval from the FDA. Generic manufacturer has settled patent litigation with the brand manufacturer. Generic availability may be sooner than patent expiration date.

NOTE: Patents of Enoxaparin (*Lovenox*) expired in 2003. As of February 2010, no generic has been approved or tentatively approved.

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More. . .

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New Drugs Approved by the FDA in 2010

This is a running list of the new drugs approved by the FDA in 2010. We will continue to update this list throughout the year. The first section lists new molecular entities as they are approved in 2010...and the second and third sections list significant new biologicals and significant new dosage forms of previously approved drugs. Some of these drugs are not yet commercially available. You'll also find a list of important drug withdrawals of 2010. Descriptions and advice about using the most significant products appear in the monthly issues of *Pharmacist's Letter*, *Pharmacy Technician's Letter*, and *Prescriber's Letter*...and more details can be found in our *Detail-Documents*. Subscribers can get the *Detail-Documents* from www.pharmacistsletter.com, www.pharmacytechniciansletter.com, and www.prescribersletter.com.

New Molecular Entities

BRAND	GENERIC	COMPANY	DESCRIPTION
Ampyra	dalfampridine	Acorda Therap.	A potassium channel blocker to improve walking in patients with multiple sclerosis.
Asclera	polidocanol	BioForm Medical	An injectable agent for small varicose veins (spider veins and reticular veins).
Carbaglu	carglumic acid	Orphan Europe	A CPS 1 activator for elevated ammonia levels due to N-acetylglutamate synthase deficiency.
Cysview	hexaminolevulinate	Photocure ASA	An optical imaging agent for bladder instillation to detect bladder cancer.
Jevtana	cabazitaxel	Sanofi-aventis	A microtubule inhibitor for advanced prostate cancer.
Lastacaft	alcaftadine	Vistakon Pharma.	An ophthalmic antihistamine for allergic conjunctivitis.
Natazia	estradiol valerate/ dienogest	Bayer HealthCare	A four-phasic, 28-day oral contraceptive with two placebo tablets.
Victoza	liraglutide	Novo Nordisk	A GLP-1 agonist to improve glucose control in type 2 diabetes.
VPRIV	velaglucerase alfa	Shire	An enzyme replacement therapy for type 1 Gaucher disease.
Zortress	everolimus	Novartis	An immunosuppressant for prevention of organ rejection (kidney transplant).

Significant New Biologicals

BRAND	GENERIC	COMPANY	DESCRIPTION
Actemra	tocilizumab	Genentech	An interleukin-6 inhibitor for moderate to severe rheumatoid arthritis.
Lumizyme	alglucosidase alfa	Genzyme	An enzyme needed for muscle function with late-onset Pompe disease.
Menveo	meningococcal vaccine	Novartis	A vaccine to prevent meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in persons 11 to 55 years of age.
Prevnar 13	pneumococcal 13-valent conjugate vaccine	Wyeth	A vaccine to prevent *Streptococcus pneumoniae*-related infections in children 6 weeks through 5 years.
Prolia	denosumab	Amgen	A RANK ligand inhibitor for treatment of postmenopausal osteoporosis.
Provenge	sipuleucel-T	Dendreon	Autologous cellular immunotherapy for treatment of advanced prostate cancer.
Xiaflex	collagenase clostridium histolyticum	Auxilium Pharm.	A proteolytic enzyme for treatment of Dupuytren's contracture (a progressive hand disease which affects connective tissue in the palm of the hand).

PHARMACIST'S LETTER

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PRESCRIBER'S LETTER

Significant New Dosage Forms

BRAND	GENERIC	COMPANY	DESCRIPTION
Butrans	buprenorphine	Purdue Pharma	Transdermal patch for moderate to severe chronic pain.
Cayston	aztreonam	Gilead	Inhaled antibiotic for cystic fibrosis patients with *Pseudomonas aeruginosa*.
Cuvposa	glycopyrrolate	Shionogi Pharma	Oral solution for chronic drooling in children (3 to 16 years) with neurologic disorders.
Differin	adapalene	Galderma	First retinoid lotion formulation for acne.
Dulera	mometasone/ formoterol	Schering	Combination steroid/long acting beta-agonist inhaler for asthma.
Exalgo	hydromorphone	Covidien	New extended-release opioid for moderate to severe chronic pain.
Jalyn	dutasteride/ tamsulosin	GSK	New combination of a 5-alpha-reductase inhibitor and an alpha-blocker for treatment of benign prostatic hyperplasia (BPH).
Lyrica	pregabalin	Pfizer	New oral solution formulation.
Mirapex ER	pramipexole	Boehringer Ingelheim	New extended-release formulation for Parkinson's disease.
Namenda XR	memantine	Forest Labs	New extended-release formulation for moderate to severe Alzheimer's disease.
Oleptro	trazodone	Labopharm	New extended-release formulation for depression.
Oravig	miconazole	Strativa Pharma.	Buccal tablet formulation for oropharyngeal candidiasis.
Silenor	doxepin	Somaxon Pharma	New 3 mg and 6 mg tablets for treatment of insomnia.
Sprix	ketorolac	Roxro Pharma	Nasal spray formulation for moderate to moderately severe pain.
Staxyn	vardenafil	GSK/Schering	New orally disintegrating tablet formulation for erectile dysfunction.
Tribenzor	olmesartan/ amlodipine/hydro-chlorothiazide	Daiichi Sankyo	Combination ARB, calcium channel blocker, and diuretic for treatment of hypertension.
Vimovo	naproxen/ esomeprazole	AstraZeneca	NSAID/PPI combination for arthritis patients at risk of NSAID-associated gastric ulcers.
Vimpat	lacosamide	UCB	New oral solution for partial-onset seizures.
Zuplenz	ondansetron	Strativa Pharma.	An oral soluble film formulation for prevention of nausea and vomiting.
Zymaxid	gatifloxacin	Allergan	A 0.5% ophthalmic solution for bacterial conjunctivitis.

Important Drug Withdrawals

BRAND	GENERIC	COMPANY	DESCRIPTION
Mylotarg	gemtuzumab ozogamicin	Pfizer	Withdrawn from the market due to safety concerns and lack of clinical benefit.

Pipeline Information

1. Briakinumab (ABT-874)-psoriasis
2. Retigabine-neuronal potassium channel opener for the adjunctive treatment of refractory partial onset seizures in adults.
3. Eliglustat-type 1 Gaucher disease.
4. Taliglucerase –IV enzyme replacement therapy for the treatment of Gaucher disease.
5. Benlysta-human monoclonal antibody being developed for the treatment of systemic lupus erythematosus (SLE).
6. Traficet-EN (CCX282)-prevents inflammation associated with Crohn's disease.
7. Mipomersen-lipid lowering.
8. Dapagliflozin-SGLT inhibitor for treatment of type 2 diabetes.
9. Cladribine-oral medication for multiple sclerosis.
10. Ticagrelor-inhibits platelet activity.
11. Carisbamate-epilepsy.
12. Ceftaroline-community acquired bacterial pneumonia and treatment of complicated skin and skin structure infections.
13. Bupropion/naltrexone-obesity.
14. Bapineuzumab-Alzheimer's disease.
15. Agomelatine-major depressive disorder.
16. Teplizumab-type 1 diabetes.
17. Zonisamide/bupropion-obesity.

Medications used to treat ADD/ADHD Utilization 07/01/09 to 06/30/10

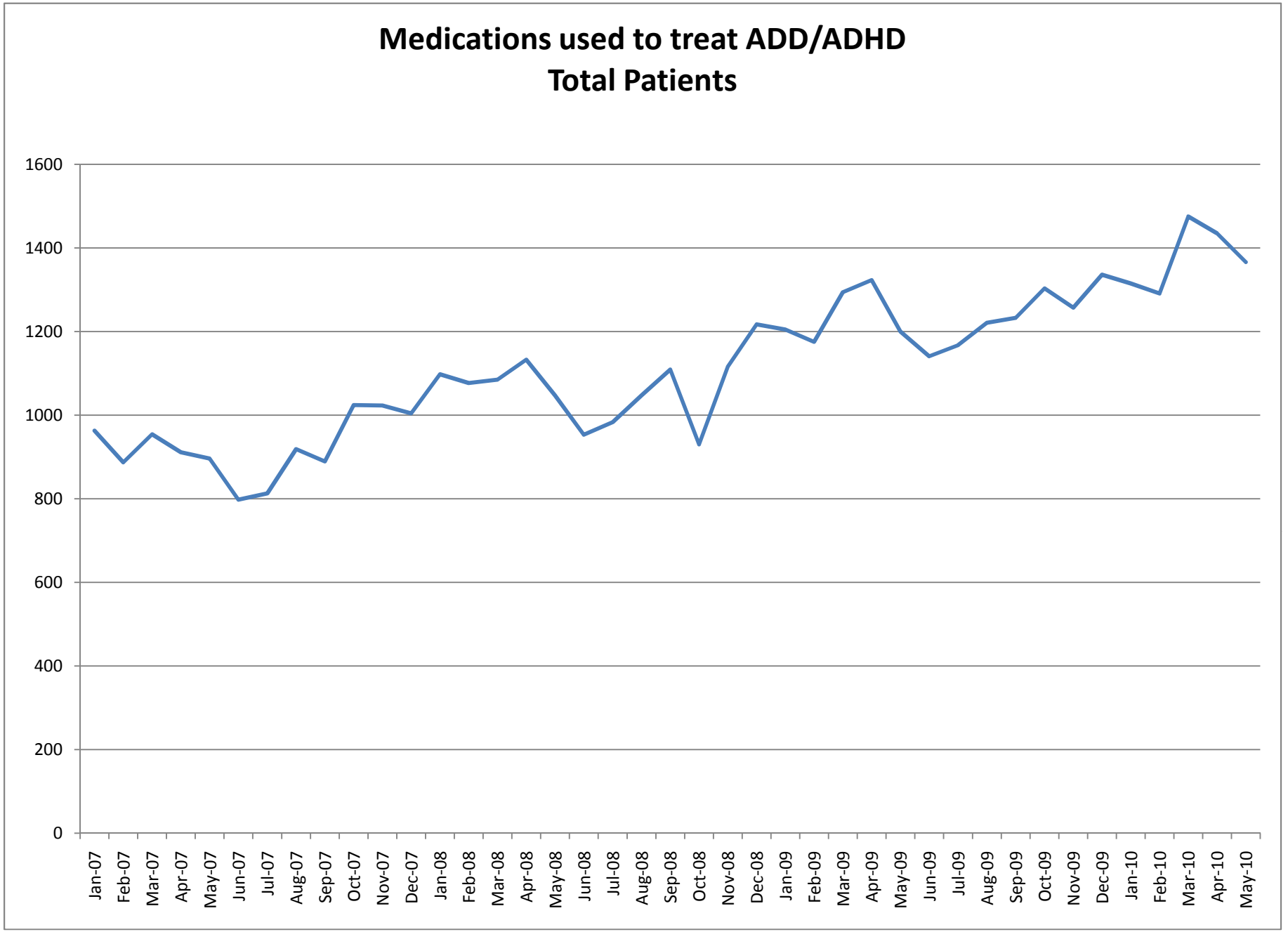
Label Name	Rx Num	Total Reimb Amt
ADDERALL 10 MG TABLET	2	$8.80
ADDERALL 20 MG TABLET	13	$5,257.79
ADDERALL XR 10 MG CAPSULE	283	$52,040.04
ADDERALL XR 15 MG CAPSULE	218	$42,277.36
ADDERALL XR 20 MG CAPSULE	569	$131,695.64
ADDERALL XR 25 MG CAPSULE	234	$45,777.78
ADDERALL XR 30 MG CAPSULE	357	$77,594.46
ADDERALL XR 5 MG CAPSULE	147	$26,084.07
AMPHETAMINE SALTS 10 MG TAB	660	$9,911.84
AMPHETAMINE SALTS 12.5 MG TB	20	$2,319.93
AMPHETAMINE SALTS 15 MG TAB	90	$2,897.75
AMPHETAMINE SALTS 20 MG TABLET	415	$8,713.31
AMPHETAMINE SALTS 30 MG TAB	193	$3,722.57
AMPHETAMINE SALTS 5 MG TAB	539	$7,777.34
CONCERTA 18 MG TABLET SA	2241	$287,821.68
CONCERTA 27 MG TABLET SA	2167	$289,020.01
CONCERTA 36 MG TABLET SA	5846	$1,012,823.52
CONCERTA 54 MG TABLET SA	4101	$609,021.73
D-AMPHETAMINE 10 MG CAP SA	218	$18,323.32
D-AMPHETAMINE ER 15 MG CAPSULE	153	$15,644.99
D-AMPHETAMINE ER 5 MG CAPSULE	64	$3,660.20
DAYTRANA 10 MG/9 HR PATCH	144	$22,530.15
DAYTRANA 15 MG/9 HR PATCH	165	$27,793.80
DAYTRANA 20 MG/9 HOUR PATCH	203	$33,158.96
DAYTRANA 30 MG/9 HOUR PATCH	225	$36,741.92
DESOXYN 5 MG TABLET	16	$27,629.16
DEXEDRINE SPANSULE 10 MG	12	$873.91
DEXEDRINE SPANSULE 15 MG	14	$1,272.52
DEXEDRINE SPANSULE 5 MG	1	$202.89
DEXMETHYLPHENIDATE 10 MG TAB	118	$4,982.62
DEXMETHYLPHENIDATE 2.5 MG TAB	88	$1,873.27
DEXMETHYLPHENIDATE 5 MG TAB	195	$6,525.80
DEXTROAMPHETAMINE 10 MG TAB	173	$3,731.10
DEXTROAMPHETAMINE 5 MG TAB	66	$1,392.75
FOCALIN 10 MG TABLET	97	$5,569.95
FOCALIN 2.5 MG TABLET	13	$392.56
FOCALIN 5 MG TABLET	164	$5,891.42
FOCALIN XR 10 MG CAPSULE	1375	$185,497.51
FOCALIN XR 15 MG CAPSULE	966	$143,963.04
FOCALIN XR 20 MG CAPSULE	1477	$219,210.26
FOCALIN XR 5 MG CAPSULE	599	$92,822.06
METADATE CD 10 MG CAPSULE	101	$13,784.71
METADATE CD 20 MG CAPSULE	305	$38,509.10

Label Name	Rx Num	Total Reimb Amt
METADATE CD 30 MG CAPSULE	143	$18,901.58
METADATE CD 40 MG CAPSULE	77	$11,702.98
METADATE CD 50 MG CAPSULE	18	$3,805.66
METADATE CD 60 MG CAPSULE	17	$3,524.34
METADATE ER 20 MG TABLET	1	$12.13
METHYLIN 10 MG CHEWABLE TABLET	20	$3,972.72
METHYLIN 10 MG TABLET	664	$9,039.05
METHYLIN 10 MG/5 ML SOLUTION	18	$3,906.56
METHYLIN 2.5 MG CHEWABLE TAB	50	$6,427.20
METHYLIN 20 MG TABLET	260	$5,809.32
METHYLIN 5 MG CHEWABLE TABLET	35	$4,118.32
METHYLIN 5 MG TABLET	645	$6,141.25
METHYLIN 5 MG/5 ML SOLUTION	24	$4,009.90
METHYLIN ER 10 MG TABLET	79	$2,147.50
METHYLIN ER 20 MG TABLET	160	$2,372.14
METHYLPHENIDATE 10 MG TABLET	281	$3,744.49
METHYLPHENIDATE 20 MG TABLET	104	$2,055.91
METHYLPHENIDATE 5 MG TABLET	300	$2,970.49
METHYLPHENIDATE ER 20 MG TAB	127	$1,906.66
PROVIGIL 100 MG TABLET	68	$21,114.04
PROVIGIL 200 MG TABLET	413	$194,033.98
RITALIN 20 MG TABLET	12	$1,595.36
RITALIN LA 10 MG CAPSULE	99	$14,517.74
RITALIN LA 20 MG CAPSULE	299	$38,915.87
RITALIN LA 30 MG CAPSULE	253	$36,831.54
RITALIN LA 40 MG CAPSULE	185	$26,118.36
STRATTERA 10 MG CAPSULE	364	$61,534.98
STRATTERA 100 MG CAPSULE	94	$16,535.06
STRATTERA 18 MG CAPSULE	479	$74,658.22
STRATTERA 25 MG CAPSULE	1176	$165,887.61
STRATTERA 40 MG CAPSULE	1453	$229,968.09
STRATTERA 60 MG CAPSULE	968	$144,345.04
STRATTERA 80 MG CAPSULE	526	$85,745.39
VYVANSE 20 MG CAPSULE	664	$81,457.69
VYVANSE 30 MG CAPSULE	1536	$192,525.72
VYVANSE 40 MG CAPSULE	904	$113,793.66
VYVANSE 50 MG CAPSULE	1363	$174,411.02
VYVANSE 60 MG CAPSULE	660	$85,933.31
VYVANSE 70 MG CAPSULE	1243	$156,782.92
Totals 5,303 recipients	**40829**	**$5,540,017.39**

Summary by Age

Age	Recip Count	Rx Count	Total Dollars
3	9	32	$2,983.29
4	53	272	$27,299.80
5	105	660	$72,842.48
6	201	1369	$159,174.51
7	303	2329	$290,787.25
8	432	3515	$440,036.18
9	448	3955	$523,356.86
10	450	3915	$492,707.92
11	422	3582	$473,918.94
12	405	3593	$480,754.27
13	349	2914	$402,600.80
14	376	2997	$436,322.82
15	324	2466	$363,739.75
16	308	2183	$306,060.26
17	285	1809	$286,651.02
18	220	1288	$174,202.29
19	100	532	$79,904.16
20	41	238	$32,985.13
21	31	211	$32,375.68
22	27	187	$25,859.51
23	18	104	$13,781.12
24	20	96	$20,649.45
25	33	221	$32,185.75
26	19	86	$9,420.55
27	15	90	$7,710.47
28	18	116	$16,661.43
29	21	119	$17,101.00
30	22	137	$17,920.20
31	15	76	$6,144.25
32	21	156	$14,103.16
33	13	66	$7,243.33
34	13	67	$8,031.70
35	15	114	$15,387.74
36	8	77	$10,281.77
37	17	88	$11,466.03
38	13	85	$34,268.24
39	10	98	$7,415.27
40	11	57	$13,560.94
41	11	55	$12,202.20
42	4	14	$850.89
43	8	91	$12,445.40
44	4	57	$8,931.32
45	9	54	$5,993.10
46	6	46	$16,477.05
47	9	106	$17,110.66

Age	Recip Count	Rx Count	Total Dollars
48	7	30	$3,836.59
49	2	17	$5,686.05
50	6	33	$7,974.72
51	7	34	$5,887.11
52	7	78	$4,731.23
53	1	10	$342.70
54	2	11	$1,453.79
55	2	5	$544.49
56	4	49	$26,883.81
57	5	95	$18,087.87
58	4	21	$4,383.05
59	5	28	$8,296.53
60	1	12	$234.12
61	2	13	$315.11
62	2	27	$348.38
63	2	31	$540.61
64	1	11	$7,927.02
65	1	1	$638.27


Medications used to treat ADD/ADHD
Total Patients
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1400
1200
1000
800
600
400
200
0
Jan-07
Feb-07
Mar-07
Apr-07
May-07
Jun-07
Jul-07
Aug-07
Sep-07
Oct-07
Nov-07
Dec-07
Jan-08
Feb-08
Mar-08
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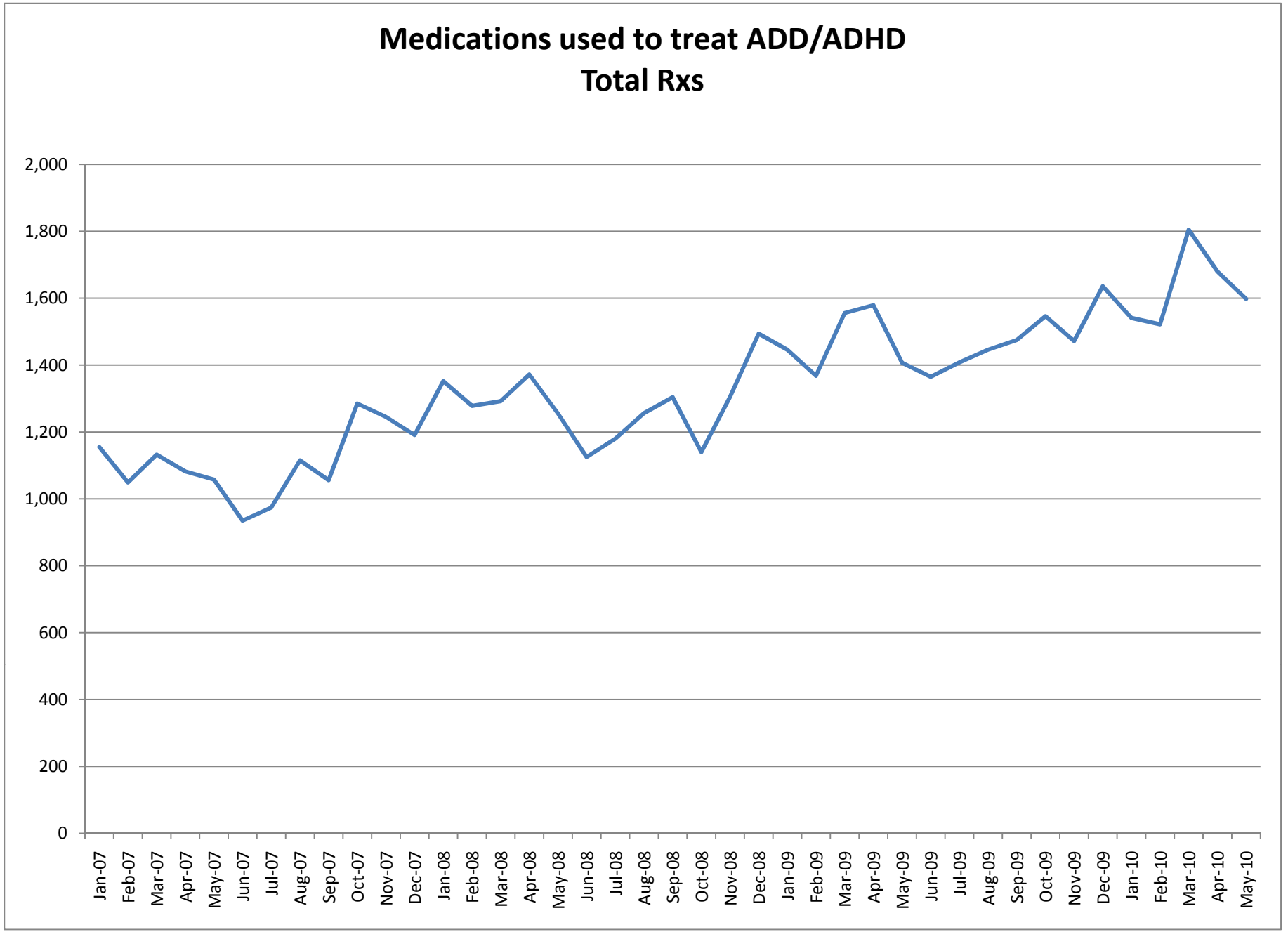
Medications used to treat ADD/ADHD
Total Rxs
2,000
1,800
1,600
1,400
1,200
1,000
800
600
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Jan-07
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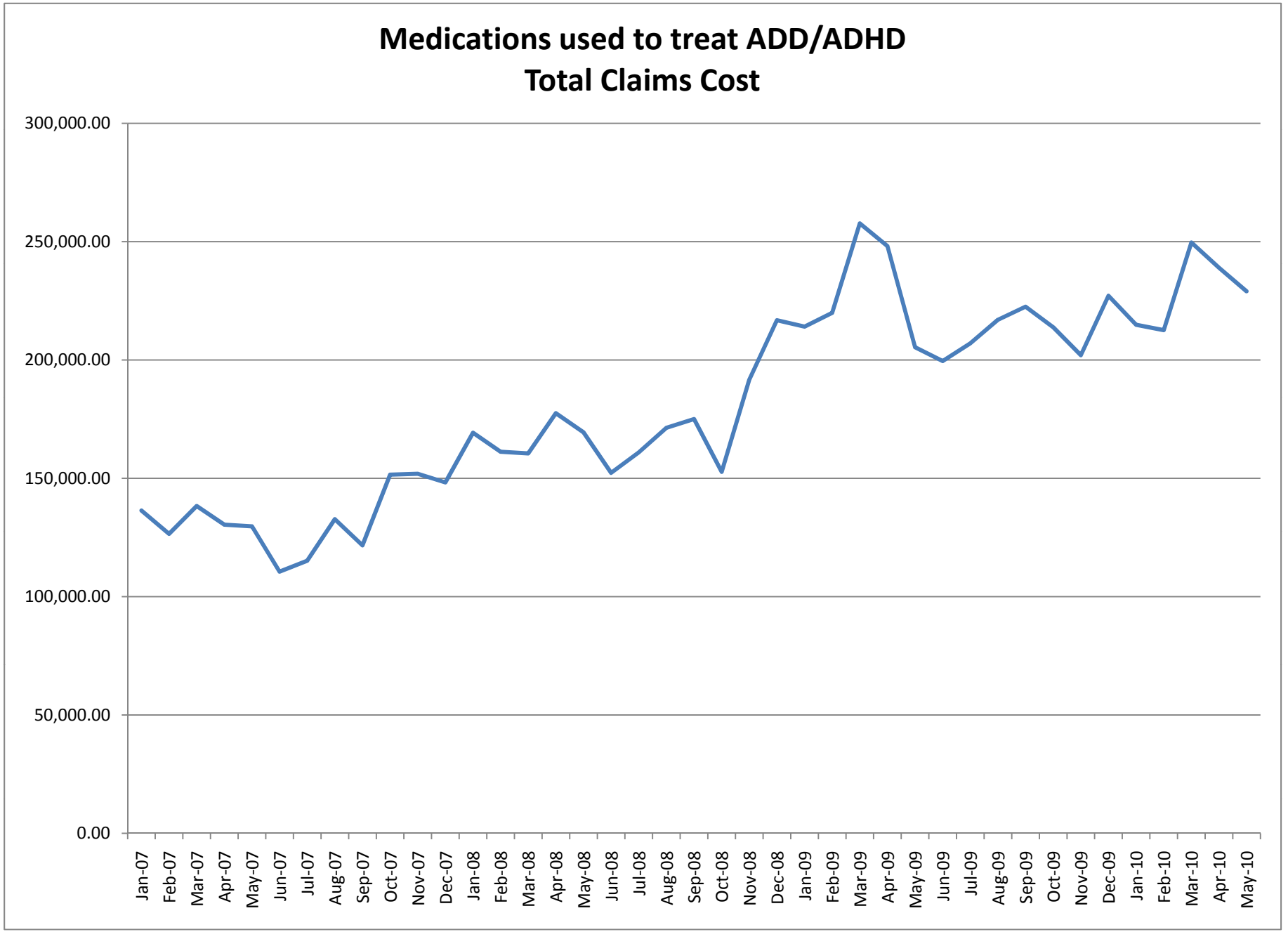
Medications used to treat ADD/ADHD
Total Claims Cost
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250,000.00
200,000.00
150,000.00
100,000.00
50,000.00
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Jan-07
Feb-07
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Mar-10
Apr-10
May-10

Consecutive Duplication for Medications used to treat ADD/ADHD
12/23/2008 - 12/22/2009
Overlap of 90 days

Unique Recipients = 47, Unique Providers = 72	Occurences
ADDERALL XR , AMPHETAMINE SALT COMBO , CONCERTA , METHYLPHENIDATE HC	4
ADDERALL XR , AMPHETAMINE SALT COMBO , DEXTROAMPHETAMINE SULFATE	7
ADDERALL XR , AMPHETAMINE SALT COMBO , STRATTERA	3
ADDERALL XR , AMPHETAMINE SALT COMBO , STRATTERA	2
ADDERALL XR , AMPHETAMINE SALT COMBO , STRATTERA , VYVANSE	2
ADDERALL XR , CONCERTA , STRATTERA	3
ADDERALL XR , FOCALIN XR , STRATTERA	2
AMPHETAMINE SALT COMBO , CONCERTA , FOCALIN XR , STRATTERA	4
AMPHETAMINE SALT COMBO , METHYLIN , VYVANSE	5
AMPHETAMINE SALT COMBO , METHYLPHENIDATE HCL , VYVANSE	1
CONCERTA , DEXTROAMPHETAMINE SULFATE , STRATTERA , VYVANSE	1
CONCERTA , FOCALIN , FOCALIN XR , METHYLIN	2
CONCERTA , FOCALIN , METHYLIN	1
CONCERTA , FOCALIN XR , METHYLPHENIDATE HCL	1
CONCERTA , METHYLIN , METHYLPHENIDATE HCL	2
CONCERTA , METHYLIN , METHYLPHENIDATE HCL	1
CONCERTA , METHYLIN , STRATTERA	2
CONCERTA , METHYLIN , STRATTERA	4
CONCERTA , METHYLIN , STRATTERA	4
CONCERTA , METHYLIN , STRATTERA	1
CONCERTA , METHYLIN , STRATTERA	1
CONCERTA , METHYLIN , STRATTERA	1
CONCERTA , METHYLIN , STRATTERA	1
CONCERTA , METHYLPHENIDATE HCL , STRATTERA	2
DAYTRANA , FOCALIN XR , STRATTERA , VYVANSE	1
DAYTRANA , METADATE CD , METHYLIN	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	1
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	3
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	4
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR	4
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR , STRATTERA	2
DEXMETHYLPHENIDATE HCL , FOCALIN , FOCALIN XR , STRATTERA	1
DEXMETHYLPHENIDATE HCL , FOCALIN , RITALIN LA	1
DEXMETHYLPHENIDATE HCL , FOCALIN XR , STRATTERA	1
DEXMETHYLPHENIDATE HCL , FOCALIN XR , STRATTERA	2
DEXTROAMPHETAMINE SULFATE , STRATTERA , VYVANSE	2
FOCALIN , FOCALIN XR , STRATTERA	2
METADATE CD , METHYLIN , METHYLPHENIDATE HCL	2
METADATE CD , METHYLIN , METHYLPHENIDATE HCL	1
METHYLIN , METHYLIN ER , METHYLPHENIDATE SR	2
METHYLIN , METHYLIN ER , METHYLPHENIDATE SR , STRATTERA	2
METHYLIN , METHYLPHENIDATE HCL , RITALIN LA	2
METHYLIN , METHYLPHENIDATE HCL , RITALIN LA	4

Consecutive Duplication for Medications used to treat ADD/ADHD
12/23/2008 - 12/22/2009
Overlap of 90 days

Provider Specialty	Count
Family Practice	25
Pediatrician	17
Psychiatrist	15
Nurse Practitioner	11

Examples of Restrictions in other States
Medications used to treat ADD/ADHD

Example 1:

Preferred agents will be approved for payment for participants over 3 years old with a documented diagnosis of ADD/ADHD or narcolepsy, who do not have a history of opioid abuse; opioid, amphetamine, cocaine, or hallucinogenic dependence; or any other contraindications to stimulant use.

Non-preferred agents will be approved for payment only after documented failure of one preferred agent. Daytrana will only be considered if participant is unable to take oral therapy.

Example 2:

STIMULANTS AND RELATED DRUGS
(Implementation 11/12/09)

Note: Patients on non-preferred stimulants prior to the PDL are eligible for "grand-fathering."

QL= quantity limits may apply to this class.

CNS STIMULANTS	
ADDERALL XR (amphetamine salt combination) amphetamine salt combination ER amphetamine salt combination IR CONCERTA (methylphenidate) dexmethylphenidate dextroamphetamine FOCALIN (dexmethylphenidate) FOCALIN XR (dexmethylphenidate) METADATE CD (methylphenidate) methylphenidate methylphenidate ER	DAYTRANA (methylphenidate) DESOXYN (methamphetamine) PROCENTRA (dextroamphetamine) RITALIN LA (methylphenidate) VYVANSE (lisdexamfetamine)
MISCELLANEOUS	
	STRATTERA (atomoxetine) INTUNIV (guanfacine)[Not Reviewed]

Example 3:

Stimulants	dextroamphetamine methamphetamine mixed amphetamines dexmethylphenidate methylphenidate lisdexamfetamine dimesylate Methylphenidate Transdermal	Dexedrine, Dextristat Desoxyn Adderall, Adderall XR Focalin Methylin, Metadate, Ritalin Vyvanse	Obesity is not a covered diagnoses. Use for ADHD, Narcolepsy and other covered diagnoses will be approved within the doses recommended in

Example 4:

STIMULANTS	AMPHETAMINES		Clients must have a diagnosis for ADD, ADHD, narcolepsy, obstructive sleep apnea, shift work sleep disturbance, MS fatigue (see MS Fatigue criteria below), or refractory depression (see refractory depression criteria below). Diagnosis of MS fatigue will require a fatigue severity scale score of 5.0, a 60-day trial of amantadine and discontinuation of medications that may contribute to drowsiness and fatigue. Diagnosis of refractory depression will require a 6-week trial and failure of an antidepressant (monotherapy) and continued concomitant use of an antidepressant with the stimulant. Prior Authorization will be required for clients under the age of 5. Claims will require Prior Authorization if clients have a history of the following: glaucoma, cardiac arrhythmias, arteriosclerosis, untreated hypertension, untreated hyperthyroidism, substance abuse, or current MAO inhibitor use. Dosing limits apply (150% of labeled max). Trial and failure of two (2) preferred agents (each from a different class: methylphenidate, amphetamine, stimulant like) greater than or equal to a 30 day supply in the last 12 months will be required before approval can be given for a non-preferred agent.
	LONG ACTING AMPHETAMINES		
		ADDERALL XR*	
		VYVANSE	
	IMMEDIATE RELEASE AMPHETAMINES		
		amphetamine salts combo	
		dextroamphetamine	
	STIMULANT LIKE		
		STRATTERA	
	METHYLPHENIDATES		
	LONG ACTING METHYLPHENIDATES		
		CONCERTA	
		FOCALIN XR	
		methylin ER	
		methylphenidate ER/CR/SR	
	IMMEDIATE RELEASE METHYLPHENIDATES		
		FOCALIN*	
		methylin (tabs)	
		methylphenidate	

Example 5:

Therapeutic Drug Class	Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred Products will be approved for one year unless otherwise stated.)
STIMULANTS and ADHD *Effective 10/1/2009* *(see note for mixed-amphetamine XR)*	**No Prior Authorization Required (as long as age limitations are met)** CONCERTA dexmethylphenidate (generic Focalin) FOCALIN XR methylphenidate (generic RITALIN) methylphenidate SR (generic for Ritalin SR) mixed-amphetamine salts (generic Adderall) mixed-amphetamine salts XR (generic Adderall XR – effective 11/1/2009) VYVANSE	**Prior Authorization Required** ADDERALL (brand only) ADDERALL XR (brand) DAYTRANA DEXEDRINE FOCALIN (brand) PROVIGIL METADATE CD METADATE ER RITALIN (brand only) STRATTERA INTUNTV (guanfacine) DESOXYN (methamphetamine)	Non-preferred agents will be approved for clients who have documented lack of efficacy with two Preferred products in the last 12 months, however, certain exceptions exist for Daytrana, Nuvigil, Provigil and Strattera (see criteria below). Also, clients age 3-5 only need to fail on one Preferred product. Approval may also be granted for clients who are unable to take Preferred products due to allergy, intolerable side effects, contraindications or significant drug-drug interaction. In addition: Non-Preferred agents will only be approved for FDA and official compendium indications. ▪ Strattera will be approved for clients with a diagnosis of ADHD and ADD. ▪ Provigil will be approved for Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, Shift Work Sleep Disorder, Multiple Sclerosis related fatigue or ADHD. ▪ Nuvigil will be approved for obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder. ▪ All other Non-Preferred products will be approved for clients with a diagnosis of ADD, ADHD, Narcolepsy, Multiple Sclerosis related fatigue, or traumatic brain injury. And Non-Preferred agents will only be approved for FDA approved age limitations. ▪ Provigil will be approved for clients 16 years of age and older. ▪ Nuvigil will be approved for clients 17 years of age and older. ▪ Adderall, Dexedrine and Dextrostat will be approved for clients 3 years of age and older. ▪ All other medications in this class will be approved for clients 6 years of age and older. Daytrana: Daytrana will be approved for clients without failure on two Preferred products if the client has difficulty swallowing. Strattera: Clients with ADD or ADHD will not need to fail on two Preferred products if the client also has one of the following conditions: history of substance abuse (or family history of substance abuse), tics, Tourette's syndrome, anxiety, low weight or OCD. If a client does not have one of these additional conditions, the client will need to fail on two Preferred products. Only one capsule per day per strength will be approved.

Example 6:

Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (ADD/ADHD) Agents

Preferred agents with criteria:

- Amphetamine salts extended-release Capsule (Adderall XR)
- Amphetamine salts Tablet (Adderall)
- Atomoxetine HCl (Strattera)
- Dexmethylphenidate HCl extended-release Capsule (Focalin XR)
- Dexmethylphenidate HCl Tablet (Focalin)
- Dextroamephetamine sulfate Tablet (Dexedrine Tablet, Dextrostat)
- Lisdexamfetamine dimesylate (Vyvanse)
- Methylphenidate extended-release Patch (Daytrana)
- Methylphenidate extended-release Tablet (Concerta)
- Methylphenidate HCl swallow Tablet (Ritalin)

Non-preferred agents:

- Dextroamephetamine sulfate extended-release Capsule (Dexedrine Spansule)
- Dextroamphetamine sulfate Solution (Liquadd, Procentra)
- Guanfacine HCl extended-release Tablet (Intuniv ER)
- Methamphetamine HCl (Desoxyn)
- Methylphenidate HCl chewable Tablet (Methylin)
- Methylphenidate HCl extended-release Capsule (Metadate CD, Ritalin LA)
- Methylphenidate HCl extended-release Tablet (Metadate ER, Ritalin SR)
- Methylphenidate HCl Solution (Methylin)

Approval criteria for preferred agents with criteria:

Atomoxetine

- No therapeutic duplication with a different ADD/ADHD with different GCN in history with >25% remaining days supply

Dexmethylphenidate immediate release

- No therapeutic duplication with atomoxetine in history with >25% remaining days supply

All Extended Release CII Stimulants

Criteria 1:

- ≤ One therapeutic duplication with the same prescriber ID and different date of service between long-acting C-II stimulants with 75% of the last fill per 93 days

Criteria 2:

- Allow one therapeutic duplication for the same subset of drugs for the same date of service from the same prescriber from the same pharmacy for predetermined total daily max milligrams that are not commercially available:
  - Adderall XR (17459, 17468, 17469, 14635, 14636, 14637) = 35mg, 45mg, or 55mg
  - Concerta (12567, 17123, 12568, 12248) = 45mg, 63mg, 81mg, or 90mg
  - Daytrana (26801, 26802, 26803, 26804) = 25mg, 35mg 45mg, 50mg
  - Focalin XR (24733, 24734, 97111, 24735) = 25mg, 35mg

All Immediate Release CII Stimulants excluding dexmethylphenidate immediate release

- ≤ One therapeutic duplication with the same prescriber ID and different date of service between short-acting C-II stimulants with 75% of the last fill per 93 days

Example 7:

APPROVAL CRITERIA

- Both stimulants involved in the therapeutic duplication are prescribed by a psychiatrist or in consultation with a psychiatrist

AND one of the following:

- There is history of at least 2 weeks of single-drug therapy at an adequate dose of each medication involved in the therapeutic duplication in the past year

OR

- The medications involved in the therapeutic duplication are being cross tapered

DENIAL CRITERIA

- Use of two stimulants for more than 60 of the past 70 days and absence of approval criteria

SD Opiate Agonist Utilization 07/01/09 - 06/30/10

Label Name	Rx Num	Total Reimb Amt	Cost per script
ACETAMINOPHEN-COD #2 TABLET	30	$232.98	$7.77
ACETAMINOPHEN-COD #3 TABLET	3825	$33,805.80	$8.84
ACETAMINOPHEN-COD #4 TABLET	28	$633.78	$22.64
ACETAMINOPHEN-CODEINE ELIXIR	1783	$15,450.81	$8.67
ASCOMP WITH CODEINE CAPSULE	1	$24.55	$24.55
AVINZA 120 MG CAPSULE	6	$2,251.35	$375.23
AVINZA 30 MG CAPSULE	14	$1,705.55	$121.83
BELLADONNA-OPIUM 16.2-30 SUPP	9	$882.15	$98.02
BUTALBITAL COMP-CODEINE #3 CAP	46	$2,191.54	$47.64
BUTALBITAL-CAFF-APAP-COD CAP	149	$3,448.40	$23.14
CAPITAL WITH CODEINE SUSP	8	$572.42	$71.55
CODEINE SULFATE 30 MG TABLET	23	$789.75	$34.34
DARVON-N 100 MG TABLET	42	$6,528.66	$155.44
DEMEROL 50 MG/ML SYRINGE	2	$14.28	$7.14
DEMEROL 75 MG/ML SYRINGE	4	$26.00	$6.50
DILAUDID 2 MG TABLET	2	$23.50	$11.75
DURAGESIC 75 MCG/HR PATCH	1	$217.75	$217.75
EMBEDA 100-4 MG CAPSULE	9	$7,542.36	$838.04
EMBEDA 20-0.8 MG CAPSULE	26	$4,240.38	$163.09
EMBEDA 30-1.2 MG CAPSULE	7	$1,820.80	$260.11
EMBEDA 50-2 MG CAPSULE	4	$1,357.49	$339.37
EMBEDA 60-2.4 MG CAPSULE	7	$944.49	$134.93
EMBEDA 80-3.2 MG CAPSULE	2	$366.98	$183.49
ENDOCET 10-325 MG TABLET	133	$5,734.77	$43.12
ENDOCET 10-650 MG TABLET	29	$1,417.01	$48.86
ENDOCET 5-325 TABLET	74	$473.99	$6.41
ENDOCET 7.5-325 MG TABLET	27	$1,843.77	$68.29
ENDOCET 7.5-500 MG TABLET	14	$429.38	$30.67
ENDODAN 4.83-325 MG TABLET	17	$663.42	$39.02
FENTANYL 100 MCG/HR PATCH	249	$77,132.59	$309.77
FENTANYL 12 MCG/HR PATCH	83	$6,606.68	$79.60
FENTANYL 25 MCG/HR PATCH	351	$23,102.30	$65.82
FENTANYL 50 MCG/HR PATCH	309	$34,858.87	$112.81
FENTANYL 75 MCG/HR PATCH	185	$31,783.25	$171.80
FENTANYL CITRATE OTFC 200 MCG	2	$496.90	$248.45
HYDROCODONE BT-IBUPROFEN TAB	605	$18,665.34	$30.85
HYDROCODONE-APAP 10-325 TABLET	2087	$47,326.19	$22.68
HYDROCODONE-APAP 10-500 TABLET	1175	$17,822.80	$15.17
HYDROCODONE-APAP 10-650 TABLET	906	$9,270.45	$10.23
HYDROCODONE-APAP 10-660 TABLET	7	$107.70	$15.39
HYDROCODONE-APAP 10-750 TABLET	28	$665.20	$23.76
HYDROCODONE-APAP 2.5-500 TAB	42	$490.01	$11.67

SD Opiate Agonist Utilization 07/01/09 - 06/30/10

Label Name	Rx Num	Total Reimb Amt	Cost per script
HYDROCODONE-APAP 5-325 TABLET	4224	$57,344.01	$13.58
HYDROCODONE-APAP 5-500 TABLET	10686	$69,225.08	$6.48
HYDROCODONE-APAP 7.5-325 TAB	463	$10,193.45	$22.02
HYDROCODONE-APAP 7.5-500 MG/15	2400	$23,848.50	$9.94
HYDROCODONE-APAP 7.5-650 TAB	32	$552.63	$17.27
HYDROCODONE-APAP 7.5-750 TAB	189	$1,540.53	$8.15
HYDROMORPHONE 2 MG TABLET	157	$2,390.14	$15.22
HYDROMORPHONE 4 MG TABLET	106	$2,657.35	$25.07
HYDROMORPHONE 8 MG TABLET	17	$1,274.35	$74.96
KADIAN 100 MG CAPSULE SR	1	$875.00	$875.00
KADIAN 80 MG CAPSULE SR	6	$2,820.78	$470.13
KADIAN ER 10 MG CAPSULE	4	$801.40	$200.35
KADIAN ER 20 MG CAPSULE	20	$6,109.10	$305.46
KADIAN ER 30 MG CAPSULE	20	$5,883.14	$294.16
KADIAN ER 50 MG CAPSULE	21	$9,935.42	$473.12
KADIAN ER 80 MG CAPSULE	6	$2,055.28	$342.55
MAGNACET 10 MG-400 MG TABLET	1	$307.72	$307.72
MEPERIDINE 50 MG TABLET	66	$825.93	$12.51
MEPERITAB 100 MG TABLET	2	$18.51	$9.26
METHADONE 5 MG/5 ML SOLUTION	7	$343.97	$49.14
METHADONE HCL 10 MG TABLET	415	$9,631.38	$23.21
METHADONE HCL 5 MG TABLET	100	$968.99	$9.69
MORPHINE 10 MG/ML SYRINGE	4	$38.23	$9.56
MORPHINE 10 MG/ML VIAL	2	$12.06	$6.03
MORPHINE 2 MG/ML SYRINGE	1	$17.55	$17.55
MORPHINE SULF 10 MG/5 ML SOLN	22	$438.84	$19.95
MORPHINE SULF 20 MG/ML SOLN	4	$53.50	$13.38
MORPHINE SULF CR 15 MG TABLET	303	$7,873.19	$25.98
MORPHINE SULF CR 200 MG TABLET	1	$40.75	$40.75
MORPHINE SULF CR 30 MG TABLET	314	$10,195.18	$32.47
MORPHINE SULF CR 60 MG TABLET	84	$4,287.73	$51.04
MORPHINE SULF ER 100 MG TABLET	51	$4,056.93	$79.55
MORPHINE SULFATE 20 MG/ML SOLN	20	$424.63	$21.23
MORPHINE SULFATE IR 15 MG TAB	165	$1,833.37	$11.11
MORPHINE SULFATE IR 30 MG TAB	100	$2,479.72	$24.80
NUCYNTA 100 MG TABLET	19	$6,200.35	$326.33
NUCYNTA 50 MG TABLET	97	$15,249.48	$157.21
NUCYNTA 75 MG TABLET	52	$11,582.12	$222.73
OPANA 10 MG TABLET	46	$28,367.53	$616.69
OPANA 5 MG TABLET	9	$1,445.48	$160.61
OPANA ER 10 MG TABLET	92	$17,906.76	$194.64
OPANA ER 15 MG TABLET	13	$3,757.44	$289.03

SD Opiate Agonist Utilization 07/01/09 - 06/30/10

Label Name	Rx Num	Total Reimb Amt	Cost per script
OPANA ER 20 MG TABLET	69	$24,771.96	$359.01
OPANA ER 30 MG TABLET	17	$8,555.66	$503.27
OPANA ER 40 MG TABLET	65	$42,565.99	$654.86
OPANA ER 5 MG TABLET	9	$715.67	$79.52
OPANA ER 7.5 MG TABLET	5	$819.59	$163.92
ORAMORPH SR 60 MG TABLET	1	$39.55	$39.55
OXYCODONE HCL 10 MG TABLET	16	$1,035.73	$64.73
OXYCODONE HCL 15 MG TABLET	271	$15,300.42	$56.46
OXYCODONE HCL 20 MG/ML SOLN	2	$26.65	$13.33
OXYCODONE HCL 30 MG TABLET	55	$5,237.51	$95.23
OXYCODONE HCL 5 MG CAPSULE	471	$10,646.24	$22.60
OXYCODONE HCL 5 MG TABLET	1122	$27,627.21	$24.62
OXYCODONE HCL 5 MG/5 ML SOL	13	$193.41	$14.88
OXYCODONE HCL CR 10 MG TABLET	104	$8,841.31	$85.01
OXYCODONE HCL CR 20 MG TABLET	239	$41,315.09	$172.87
OXYCODONE HCL CR 40 MG TABLET	110	$36,514.32	$331.95
OXYCODONE HCL CR 80 MG TABLET	89	$34,173.88	$383.98
OXYCODONE-APAP 10-325 MG TAB	383	$20,016.77	$52.26
OXYCODONE-APAP 10-650 MG TAB	43	$1,654.69	$38.48
OXYCODONE-APAP 5-325 MG TAB	4099	$29,027.22	$7.08
OXYCODONE-APAP 5-500 MG CAP	261	$1,611.05	$6.17
OXYCODONE-APAP 7.5-325 MG TAB	78	$3,396.42	$43.54
OXYCODONE-APAP 7.5-500 MG TAB	21	$501.99	$23.90
OXYCONTIN 10 MG TABLET	349	$36,034.49	$103.25
OXYCONTIN 15 MG TABLET	69	$8,994.32	$130.35
OXYCONTIN 20 MG TABLET	623	$142,645.66	$228.97
OXYCONTIN 30 MG TABLET	196	$59,895.77	$305.59
OXYCONTIN 40 MG TABLET	474	$205,064.45	$432.63
OXYCONTIN 60 MG TABLET	138	$87,098.43	$631.15
OXYCONTIN 80 MG TABLET	167	$192,469.94	$1,152.51
OXYIR 5 MG CAPSULE	12	$330.40	$27.53
PANLOR DC CAPSULE	6	$303.34	$50.56
PERCOCET 2.5-325 MG TABLET	4	$383.97	$95.99
PERCOCET 5-325 MG TABLET	1	$43.73	$43.73
PROPOXYPHEN-APAP 100-650 MG TB	5038	$41,065.59	$8.15
PROPOXYPHENE HCL 65 MG CAP	380	$6,443.80	$16.96
PROPOXYPHENE-APAP 50-325 MG TB	9	$192.02	$21.34
ROXICET 5-325 ORAL SOLUTION	11	$298.24	$27.11
ROXICET 5-325 TABLET	91	$615.69	$6.77
ROXICODONE 15 MG TABLET	1	$11.95	$11.95
ROXICODONE 30 MG TABLET	1	$4.57	$4.57
ROXICODONE 5 MG TABLET	2	$43.06	$21.53

SD Opiate Agonist Utilization 07/01/09 - 06/30/10

Label Name	Rx Num	Total Reimb Amt	Cost per script
ROXICODONE 5 MG/5 ML SOLUTION	1	$13.58	$13.58
RYZOLT ER 100 MG TABLET	1	$110.31	$110.31
RYZOLT ER 200 MG TABLET	7	$1,269.03	$181.29
RYZOLT ER 300 MG TABLET	1	$252.26	$252.26
TRAMADOL HCL 50 MG TABLET	6882	$63,707.47	$9.26
TRAMADOL HCL ER 100 MG TABLET	34	$3,167.01	$93.15
TRAMADOL HCL ER 200 MG TABLET	101	$17,183.90	$170.14
TRAMADOL-APAP 37.5-325 MG TAB	339	$9,923.15	$29.27
TYLENOL WITH CODEINE #3 TABLET	1	$3.48	$3.48
TYLOX 5-500 CAPSULE	10	$3,981.80	$398.18
ULTRAM 50 MG TABLET	2	$13.27	$6.64
ULTRAM ER 100 MG TABLET	76	$9,810.33	$129.08
ULTRAM ER 200 MG TABLET	100	$18,495.28	$184.95
ULTRAM ER 300 MG TABLET	238	$61,614.78	$258.89
VICODIN 5-500 TABLET	6	$33.00	$5.50
ZAMICET SOLUTION	58	$3,013.20	$51.95
Totals 14,844 recipients	**55560**	**$1,972,403.32**	

BRAND-NAME NARCOTICS PA FORM
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for a brand-name narcotic must meet the following criteria:

- **Documented failure of a 30-day trial of a generic narcotic at a dose equivalent to the brand-name narcotic being prescribed.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN MEDICAID PROVIDER NUMBER:
PHYSICIAN ADDRESS:		
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug: (must be completed)

□ EMBEDA □ OPANA □ KADIAN □ AVINZA □ EXALGO □ FENTORA □ COMBUNOX □ ONSOLIS □ MAGNACET

Qualifications for coverage:

❑ Failed therapy	Start Date:	End Date:	Dose:	Frequency:

Physician Signature:	Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAIDPROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

Top Drugs by Dollar Total 2009
Reimbursed Amount > $1,000/Rx

Description	Rx Count	Dollar Total	Dollar/Rx
FEIBA VH IMMU 1,750-3,250 UNIT	10	$428,134.84	$42,813.48
NUTROPIN AQ PEN CARTRIDGE	146	$364,550.18	$2,496.92
PULMOZYME 1 MG/ML AMPUL	155	$304,166.97	$1,962.37
TOBI 300 MG/5 ML SOLUTION	101	$256,568.42	$2,540.28
ARCALYST 220 MG INJECTION	10	$222,007.50	$22,200.75
REMODULIN 10 MG/ML VIAL	11	$216,731.75	$19,702.89
OXYCONTIN 80 MG TABLET	168	$210,283.52	$1,251.69
LIORESAL IT 40 MG/20 ML KIT	145	$168,745.14	$1,163.76
ENBREL 50 MG/ML SURECLICK SYR	89	$165,714.67	$1,861.96
ATRIPLA TABLET	106	$164,244.67	$1,549.48
HUMIRA 40 MG/0.8 ML PEN	88	$156,790.20	$1,781.71
HELIXATE FS 1,000 UNIT VIAL	10	$156,348.82	$15,634.88
COPAXONE 20 MG INJECTION KIT	59	$154,162.84	$2,612.93
HUMATROPE 24 MG CARTRIDGE	29	$148,955.50	$5,136.40
REBIF 44 MCG/0.5 ML SYRINGE	57	$140,048.06	$2,456.98
BETASERON 0.3 MG KIT	54	$135,668.86	$2,512.39
HELIXATE FS 2,000 UNIT VIAL	2	$133,301.06	$66,650.53
XOLAIR 150 MG VIAL	57	$129,563.17	$2,273.04
HUMIRA 40 MG/0.8 ML SYRINGE	72	$124,001.39	$1,722.24
XENAZINE 25 MG TABLET	21	$119,577.80	$5,694.18
AVONEX PREFILLED SYR 30 MCG	44	$106,393.22	$2,418.03
RECOMBINATE 801-1,240 UNIT VL	5	$88,835.71	$17,767.14
GENOTROPIN 12 MG CARTRIDGE	31	$80,092.69	$2,583.64
ENBREL 50 MG/ML SYRINGE	46	$78,742.46	$1,711.79
VENTAVIS 10 MCG/1 ML SOLUTION	8	$72,699.65	$9,087.46
NUTROPIN AQ 5 MG/ML VIAL	24	$70,020.27	$2,917.51
SUPPRELIN LA 50 MG KIT	7	$69,696.75	$9,956.68
XELODA 500 MG TABLET	46	$67,862.30	$1,475.27
REVATIO 20 MG TABLET	35	$62,860.07	$1,796.00
NUTROPIN AQ 20 MG/2ML PEN CART	25	$61,988.84	$2,479.55
ZYVOX 600 MG TABLET	40	$61,596.40	$1,539.91
GLEEVEC 100 MG TABLET	10	$58,289.67	$5,828.97
KUVAN 100 MG TABLET	25	$56,704.56	$2,268.18
TRACLEER 125 MG TABLET	10	$54,039.70	$5,403.97
HUMATE-P 2,400 UNITS KIT	3	$53,369.95	$17,789.98
GENOTROPIN MINIQUICK 1 MG	40	$53,076.01	$1,326.90
GENOTROPIN 5 MG CARTRIDGE	44	$52,420.52	$1,191.38
TEV-TROPIN 5 MG VIAL	6	$49,999.62	$8,333.27
GENOTROPIN MINIQUICK 2 MG	14	$47,815.96	$3,415.43
ENBREL 25 MG KIT	30	$46,251.37	$1,541.71
RECOMBINATE 401-800 UNIT VIAL	5	$44,038.81	$8,807.76
PEGASYS 180 MCG/0.5 ML CONV.PK	23	$43,428.34	$1,888.19
HUMATROPE 12 MG CARTRIDGE	16	$38,235.09	$2,389.69
VALCYTE 450 MG TABLET	17	$33,756.20	$1,985.66

Top Drugs by Dollar Total 2009
Reimbursed Amount > $1,000/Rx

Description	Rx Count	Dollar Total	Dollar/Rx
XYREM 500 MG/ML ORAL SOLUTION	21	$33,444.30	$1,592.59
NEUPOGEN 300 MCG/ML VIAL	18	$26,627.68	$1,479.32
GLEEVEC 400 MG TABLET	8	$25,056.01	$3,132.00
REMODULIN 5 MG/ML VIAL	4	$24,082.48	$6,020.62
SIMPONI 50 MG/0.5 ML PEN INJEC	13	$23,460.95	$1,804.69
HUMIRA CROHN'S STARTER PACK	5	$22,800.36	$4,560.07
NEXAVAR 200 MG TABLET	4	$22,662.48	$5,665.62
MEPRON 750 MG/5 ML SUSPENSION	18	$21,234.79	$1,179.71
NORDITROPIN NORDIFLX 15 MG/1.5	7	$21,211.90	$3,030.27
VENTAVIS 10 MCG/1 ML SOLUTION	2	$20,342.37	$10,171.19
PANCRECARB MS-16 CAPSULE EC	13	$20,259.24	$1,558.40
TOBI 300 MG/5 ML SOLUTION	5	$19,066.32	$3,813.26
DESOXYN 5 MG TABLET	18	$18,154.08	$1,008.56
CAFFEINE CIT 20 MG/ML ORAL SOL	18	$18,052.12	$1,002.90
TRIZIVIR TABLET	13	$17,618.62	$1,355.28
LUPRON DEPOT 11.25 MG 3MO KIT	9	$17,269.54	$1,918.84
GENOTROPIN MINIQUICK 1.6 MG	6	$16,897.11	$2,816.19
LUPRON DEPOT-PED 11.25 MG KIT	12	$16,744.23	$1,395.35
LOVENOX 150 MG PREFILLED SYR	6	$16,168.65	$2,694.78
ZYVOX 600 MG TABLET	6	$15,828.01	$2,638.00
KINERET 100 MG/0.67 ML SYR	11	$15,386.29	$1,398.75
VFEND 40 MG/ML SUSPENSION	11	$15,375.95	$1,397.81
GENOTROPIN MINIQUICK 0.8 MG	10	$14,153.24	$1,415.32
ORENCIA 250 MG VIAL	8	$14,097.66	$1,762.21
SENSIPAR 90 MG TABLET	13	$13,882.92	$1,067.92
GENOTROPIN MINIQUICK 1.8 MG	4	$12,931.56	$3,232.89
HUMATROPE 5 MG VIAL	10	$12,899.26	$1,289.93
APTIVUS 250 MG CAPSULE	12	$12,709.04	$1,059.09
PROCRIT 20,000 UNITS/ML VIAL	5	$12,332.90	$2,466.58
REBIF TITRATION PACK	5	$12,271.43	$2,454.29
REMODULIN 2.5 MG/ML VIAL	3	$12,043.00	$4,014.33
ARANESP 300 MCG/0.6 ML SYRINGE	5	$11,614.68	$2,322.94
CUBICIN 500 MG VIAL	5	$11,424.50	$2,284.90
CIMZIA KIT	5	$10,900.21	$2,180.04
HUMATE-P 1,200 UNITS KIT	1	$10,715.31	$10,715.31
PROGRAF 5 MG CAPSULE	4	$10,555.88	$2,638.97
VFEND 200 MG TABLET	6	$10,390.13	$1,731.69
GENOTROPIN MINIQUICK 1.4 MG	2	$9,948.86	$4,974.43
DRONABINOL 10 MG CAPSULE	8	$9,803.00	$1,225.38
TEMODAR 140 MG CAPSULE	9	$9,737.28	$1,081.92
TEMODAR 180 MG CAPSULE	4	$9,384.36	$2,346.09
ARANESP 60 MCG/ML VIAL	7	$9,246.68	$1,320.95
TEMODAR 250 MG CAPSULE	7	$9,152.13	$1,307.45
PEGINTRON REDIPEN 120 MCG	5	$9,105.12	$1,821.02
PEGINTRON REDIPEN 150 MCG	4	$8,919.58	$2,229.90

Top Drugs by Dollar Total 2009
Reimbursed Amount > $1,000/Rx

Description	Rx Count	Dollar Total	Dollar/Rx
ULTRASE MT 20 CAPSULE EC	6	$7,875.47	$1,312.58
TEMODAR 140 MG CAPSULE	1	$7,751.57	$7,751.57
ARANESP 200 MCG/0.4 ML SYRINGE	7	$7,724.98	$1,103.57
SUTENT 50 MG CAPSULE	1	$7,656.81	$7,656.81
TARCEVA 100 MG TABLET	2	$6,976.72	$3,488.36
VANCOCIN HCL 250 MG PULVULE	4	$6,963.51	$1,740.88
SPRYCEL 50 MG TABLET	1	$6,799.62	$6,799.62
NEULASTA 6 MG/0.6 ML SYRINGE	2	$6,743.48	$3,371.74
SPRYCEL 70 MG TABLET	1	$6,739.25	$6,739.25
NEUMEGA 5 MG VIAL	2	$6,582.38	$3,291.19
HUMIRA PSORIASIS STARTER PACK	2	$6,527.61	$3,263.81
PANCRECARB MS-16 CAPSULE EC	5	$6,454.45	$1,290.89
INVEGA SUSTENNA 234 MG PREF SY	4	$6,375.12	$1,593.78
LUPRON DEPOT-PED 15 MG KIT	4	$6,121.18	$1,530.30
SUCRAID 8,500 UNITS/ML SOLN	1	$6,073.96	$6,073.96
EXJADE 500 MG TABLET	1	$6,003.34	$6,003.34
CANCIDAS IV 50 MG VIAL	2	$5,298.92	$2,649.46
BENEFIX 500 UNIT VIAL	2	$4,811.00	$2,405.50
BOTOX 100 UNITS VIAL	4	$4,697.15	$1,174.29
BETASERON 0.3 MG KIT	2	$4,448.56	$2,224.28
INVEGA SUSTENNA 156 MG PREF SY	4	$4,255.36	$1,063.84
LUPRON DEPOT-PED 11.25 MG KIT	3	$4,131.24	$1,377.08
HUMATE-P 600 UNITS KIT	1	$4,107.35	$4,107.35
LUPRON DEPOT 11.25 MG 3MO KIT	3	$4,017.09	$1,339.03
NEUPOGEN 480 MCG/1.6 ML VIAL	1	$3,857.50	$3,857.50
ARIXTRA 10 MG SYRINGE	1	$3,811.04	$3,811.04
TEMODAR 100 MG CAPSULE	1	$3,622.00	$3,622.00
CAFCIT 20 MG/ML ORAL SOLN	3	$3,524.25	$1,174.75
THALOMID 50 MG CAPSULE	1	$3,399.15	$3,399.15
GENOTROPIN MINIQUICK 0.6 MG	3	$3,206.81	$1,068.94
NEUPOGEN 300 MCG/0.5 ML SYR	3	$3,154.44	$1,051.48
FEIBA VH IMMUNO 651-1,200 UNIT	1	$3,032.21	$3,032.21
NAGLAZYME 5 MG/5 ML VIAL	1	$2,992.18	$2,992.18
NEUPOGEN 300 MCG/ML VIAL	2	$2,820.26	$1,410.13
COLISTIMETHATE 150 MG VIAL	2	$2,769.50	$1,384.75
NEUMEGA 5 MG VIAL	1	$2,743.45	$2,743.45
ELAPRASE 6 MG/3 ML VIAL	2	$2,706.56	$1,353.28
TARCEVA 25 MG TABLET	2	$2,434.55	$1,217.28
PEGINTRON 150 MCG KIT	1	$2,298.82	$2,298.82
EPOGEN 10,000 UNITS/ML VIAL	2	$2,156.65	$1,078.33
TEMODAR 250 MG CAPSULE	1	$2,090.94	$2,090.94
PULMOZYME 1 MG/ML AMPUL	1	$1,861.11	$1,861.11
OCTREOTIDE ACET 200 MCG/ML VL	1	$1,355.09	$1,355.09
PROGRAF 1 MG CAPSULE	1	$1,332.16	$1,332.16
ARANESP 60 MCG/0.3 ML SYRINGE	1	$1,298.49	$1,298.49

Top Drugs by Dollar Total 2009
Reimbursed Amount > $1,000/Rx

Description	Rx Count	Dollar Total	Dollar/Rx
VFEND 50 MG TABLET	1	$1,251.66	$1,251.66
RABAVERT RABIES VACCINE KIT	1	$1,112.31	$1,112.31
AZACTAM 1 GM VIAL	1	$1,095.96	$1,095.96
Totals	**2,414**	**$6,262,804.94**	**$2,594.37**

METOZOLV ODT PRIOR AUTHORIZATION
SD DEPARTMENT OF SOCIAL SERVICES
MEDICAL SERVICES DIVISION

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-705-5391

SD Medicaid requires that patients receiving a new prescription for Metozolv must meet the following criteria:

- **Patient must try metoclopramide.**

Part I: RECIPIENT INFORMATION (To be completed by physician's representative or pharmacy):

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	

Part II: PHYSICIAN INFORMATION (To be completed by physician's representative or pharmacy):

PHYSICIAN NAME:		PHYSICIAN MEDICAID PROVIDER NUMBER:
PHYSICIAN ADDRESS:		
CITY:	PHONE: ( )	FAX: ( )

Part III: TO BE COMPLETED BY PHYSICIAN:

Requested Drug: (must be completed) **Diagnosis for this request:**			
Qualifications for coverage:			
❑ Failed metoclopramide therapy	Start Date:	End Date:	Dose:
Physician Signature:			Date:

Part IV: PHARMACY INFORMATION

PHARMACY NAME:	SD MEDICAIDPROVIDER NUMBER:
Phone: ( ):	FAX:: ( )
Drug:	NDC#:

Part V: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

South Dakota Medicaid
Pharmacotherapy Review
Statin and Statin Combinations

I. Overview

The 3-hydroxy-3-methylglutaryl-coenzyme (HMG-CoA) reductase inhibitors, also known as statins, are the most effective class of drugs for lowering serum low-density lipoprotein (LDL-C) concentrations. Depending on the agent, the statins can decrease LDL-C by 18% to 60% when used as monotherapy. The statins work by inhibiting HMG-CoA reductase, the enzyme that catalyzes the conversion of HMG-CoA to mevalonate in an early step in the biosynthesis of cholesterol. In addition to LDL-C reduction, statins lower total cholesterol as well as triglycerides, and slightly increase high-density lipoprotein (HDL-C).

Lowering total cholesterol and LDL-C and raising HDL-C is important for many reasons. Deposition of cholesterol in the arterial walls is central to the pathogenesis of atherosclerosis in the coronary arteries. A direct correlation exists between total cholesterol, LDL-C, and the risk of developing coronary heart disease (CHD). Each 1% reduction in LDL-C results in approximately a 1% decrease in the risk of a major cardiac event. An inverse relationship exists between HDL-C and the risk of developing CHD; each 1mg/dL decrease in HDL-C results in a 2-3% increase in the risk of CHD.

CHD is the single leading cause of death in America today with over 425,000 deaths in 2006. From 1996 to 2006, the death rate from CVD decreased 29.2 percent and the death rate from CHD decreased 36.4 percent. Advances have been made in the treatment of CVD, CHD and hyperlipidemia, but there is still work to be done. There are approximately 35.7 million adults in the U.S. with a total cholesterol value of 240mg/dL and greater. The direct and indirect healthcare cost for CVD in 2009 is estimated to be at $475.3 billion.

Pharmacotherapy that can lower total cholesterol and LDL-C while raising HDL-C is not only worthwhile, but extremely valuable. HMG-CoA reductase inhibitors are considered first-line agents for treating hyperlipidemia.

Table 1 lists the agents included in this review.

Table 1. Statin and Statin Combinations Included in this Review

Generic Name	Brand Name	Dosage Form/Strength	Generic Availability	Manufacturer
Atorvastatin	Lipitor®	Tablets: 10mg, 20mg, 40mg, and 80mg	No	Pfizer
Atorvastatin/amlodipine	Caduet®	Tablets: 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg, 5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg,	No	Pfizer

Generic Name	Brand Name	Dosage Form/Strength	Generic Availability	Manufacturer
		10mg/10mg, 10mg/20mg, 10mg/40mg, and 10mg/80mg		
Fluvastatin	Lescol®, Lescol XL®	Capsules: 20mg, and 40mg; Extended-release tablets: 80mg	No	Novartis
Lovastatin	Mevacor®, Altoprev®	Tablets: 10mg, 20mg, and 40mg; Extended-release tablets: 20mg, 40mg, and 60mg	Yes-Mevacor No-Altoprev	Merck, Altoprev-First Horizon, various generic companies
Lovastatin/niacin ER	Advicor®	Tablets: 500mg/20mg, 750mg/20mg, 1000mg/20mg, and 1000mg/40mg	No	Abbott
Rosuvastatin	Crestor®	Tablets: 5mg, 10mg, 20mg, and 40mg	No	AstraZeneca
Pitavastatin	Livalo®	Tablets: 1mg, 2mg, and 4mg	No	Kowa Pharmaceuticals
Pravastatin	Pravachol®	Tablets: 10mg, 20mg, 40mg, and 80mg	Yes	Bristol-Myers Squibb, various generic companies
Simvastatin	Zocor®	Tablets: 5mg, 10mg, 20mg, 40mg, and 80mg	Yes	Merck, various generic companies
Simvastatin/ezetimibe	Vytorin®	Tablets:10mg/10mg, 10mg/20mg, 10mg/40mg, and 10mg/80mg	No	Merck/Schering-Plough
Simvastatin/niacin ER	Simcor®	500mg/20mg, 500mg/40mg, 750/20mg, 1,000mg/20mg and 1,000mg/40mg	No	Abbott

II. Current Treatment Guidelines

The decision to treat hyperlipidemia generally follows the treatment guidelines of the Third Report of the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III, published in 2002 and updated in 2004. The report stresses that the intensity of treatment should be directed by the degree of cardiovascular risk. Because LDL-C is the major atherogenic lipid component, NCEP-ATP III focuses primarily on achieving target LDL-C levels. For most patients who are prescribed a statin, the target is <130 mg/dL or <100 mg/dL. In ATP-III, patients who have type 2 diabetes without CHD; peripheral or carotid vascular disease; and patients who have multiple risk factors and a 10-year risk of CHD > 20% are said to have 'CHD equivalents.' This means that the criteria for using drug therapy and the LDL-C target is the same for patients who have a history of CHD.

The 2006 update of the American Heart Association/American College of Cardiology consensus statement on secondary prevention states that an LDL-C goal of <70 mg/dL for high risk patients is a therapeutic option. Factors that place patients in the category of very high risk are the presence of established CVD plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides >200 mg/dL plus non-HDL-C >130 mg/dL with low HDL-C <40 mg/dL, and 4) patients with acute coronary syndromes. If it is not possible to attain LDL-C <70 mg/dL because of a high baseline LDL-C, it generally is possible to achieve LDL-C reductions of >50% with either statins or LDL-C lowering drug combinations. The optimal goal of <70 mg/dL does not apply to individuals who are not at high risk.

Table 2 summarizes NCEP Treatment Guidelines for LDL-C goals and cutpoints for therapeutic lifestyle changes (TLC), and pharmacotherapy in different risk categories.

Table 2. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for TLC and Pharmacotherapy

Risk Category	LDL Goal	LDL Level to Initiate TLC	LDL Level at Which to Consider Drug Therapy
CHD or CHD Risk Equivalent (10-year risk > 20%)	< 100 mg/dL	≥ 100 mg/dL	≥ 130 mg/dL (100-129 mg/dL, drug optional)*
2 or more Risk Factors (10-year risk ≤ 20%)	< 130 mg/dL	≥130 mg/dL	≥ 130 mg/dL (for 10-year risk 10-20%) > 160 mg/dL (for 10-year risk < 10%)
0-1 Risk Factors	< 160 mg/dL	≥ 160 mg/dL	≥ 190 mg/dL (160-189 mg/dL, drug optional)**

*Some authorities recommend use of LDL-C lowering drugs in this category if an LDL-C < 100 mg/dL cannot be achieved by TLC. Others prefer use of drugs that primarily modify triglycerides and HDL, e.g., nicotinic acid or fibrate. Clinical judgment may also call for deferring drug therapy in this subcategory.

**Factors that favor drug therapy after 3 months of TLC include a severe single risk factor (heavy smoking, poorly controlled hypertension, strong family history of premature CHD, or very low HDL-C), multiple life-habit risk factors and emerging risk factors, or 10-year risk approaching 10%.

III. Comparative Indications for HMG-CoA Reductase Inhibitors

The Food and Drug Administration (FDA) has approved HMG-CoA reductase inhibitors for use adjunctively with a diet restricted in saturated fat and cholesterol when diet and other nonpharmacological therapies alone have produced inadequate responses.

Table 3 summarizes the FDA-approved indications for HMG-CoA reductase inhibitors included in this review.

Table 3. FDA Approved Indications for the HMG-CoA Reductase Inhibitors

Indication	Atorvastatin	Fluvastatin/ Fluvastatin XL	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Primary prevention of CV disease in patients with multiple risk factors for CHD, diabetes, peripheral vascular disease, history of stroke, or other cerebrovascular disease to:							
Reduce angina risk	√		√				
Reduce MI risk	√				√		√
Reduce stroke risk	√						√
Reduce risk for revascularization procedures	√		√		√		√
Reduce risk of CV mortality					√		√
Secondary prevention of CV events in patients with clinically evident CHD to:							
Reduce risk of MI	√				√		√
Reduce risk of stroke	√				√		√
Reduce risk for revascularization procedures	√	√			√		√
Reduce risk of hospitalization for CHF	√						
Reduce angina risk	√						
Slow progression of coronary atherosclerosis		√	√		√	√	
Reduce risk of total mortality by reducing coronary death					√		√
Hypercholesterolemia							
Primary hyper-cholesterolemia (heterozygous familial and nonfamilial)	√	√	√	√	√	√	√
Adolescents with heterozygous familial hyper-cholesterolemia	√	√	√		√		√
Homozygous familial hyper-cholesterolemia	√					√	√

Indication	Atorvastatin	Fluvastatin/ Fluvastatin XL	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Mixed dyslipidemia (Fredrickson types IIa and IIb)	√	√	√	√	√	√	√
Hyper-triglyceridemia (Fredrickson type IV)	√				√	√	√
Primary dysbetalipo-proteinemia (Fredrickson type III)	√				√	√	√

Combination Product Indications:

1. **Amlodipine/Atorvastatin (Caduet)**
   - Amlodipine: For the treatment of hypertension, chronic stable angina, and confirmed or suspected vasospastic angina (Prinzmetal or Variant angina).
   - Atorvastatin: See indications above.

2. **Niacin (Extended Release)/Lovastatin (Advicor)**
   - Primary hypercholesterolemia/mixed dyslipidemia: For the treatment of primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Types IIa and IIb) in the following: Patients treated with lovastatin who require further TG-lowering or HDL-raising who may benefit from having niacin added to their regimen; patients treated with niacin who require further LDL-lowering who may benefit from having lovastatin added to their regimen.

3. **Niacin (Extended Release)/Simvastatin (Simcor)**
   - Hypercholesterolemia: For the reduction of total cholesterol, LDL-C, APO B, non-HDL-C, or TG, or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson type IIa and IIb) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
   - Hypertriglyceridemia: For the reduction of triglycerides in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.

4. **Ezetimibe/Simvastatin (Vytorin)**
   - Homozygous familial hypercholesterolemia: For reducing elevated total cholesterol and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments.

- Primary hypercholesterolemia: Adjunctive therapy to diet for reducing elevated total cholesterol, LDL-C, apolipoprotein B (apo B), triglycerides, and non-high-density lipoprotein cholesterol (HDL-C), and to increase HDL-C in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipidemia.

IV. Comparative Pharmacokinetic Parameters of HMG-CoA Reductase Inhibitors

Table 4. Pharmacokinetic parameters of HMG-CoA Reductase Inhibitors

	Atorvastatin	Fluvastatin/ Fluvastatin XL	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Elimination Half Life	14 hours (20-30 hours for HMG-CoA reductase inhibitory activity)	<3 hours for IR and 9 hours for ER	3 to 4 hours (IR)	12 hours	77 hours (pravastatin plus metabolites)	19 hours	
Absolute Bioavailability	~14%	24%-IR 29%-ER	<5%; BA for ER was 190% compared with IR	51%	17%	20%	<5%
Food Effect	Decreased rate and extent of absorption; not clinically significant	Decreased rate, but not extent of absorption	Decreased bio-availability (ER)	Decreased rate by 43%, but not sig-nificantly reduce extent	Decreased bio-availability; not clinically significant	Decreased rate 20%, but not extent of absorption	
Protein Binding	≥98%	98%	>95%	>99%	50%	88%	95%
Time to peak	1 to 2 hours	<1 hour (IR); 3 hours ER)	2 to 4 hours	1 hour	1 to 1.5 hours	3 to 5 hours	1.3 to 2.4 hours
Main Metabolizing Enzyme	CYP3A4 (hepatic-first pass)	CYP2C9 (75%) (hepatic- first pass)	CYP3A4 (hepatic-extensive first pass)	Marginal CYP2C9	Extensive sulfation	Minor CYP2C9	Extensive CYP3A4
Primary Route of Elimination	Bile; <2% (urine)	5% (urine); 90% (feces)	10% (urine); 83% (feces)	15% (urine); 79% (feces)	20% (urine); 70% (feces)	90% (feces)	13% (urine); 60% (feces)
Effects of Renal/Hepatic Impairment	Plasma levels ↑ in chronic alcoholic liver disease.	Plasma levels ↑ with hepatic insufficiency.	Plasma levels ↑ in severe renal disease.	Plasma concentrations are ↑ in mild to moderate hepatic im-pairment;	Potential drug accumulation with renal or hepatic insufficiency; mean AUC varied 18-	Increased plasma concentrations with severe renal impairment and hepatic	Higher systemic exposure may occur in hepatic and severe renal in-

	Atorvastatin	Fluvastatin/ Fluvastatin XL	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
				rate and extent of absorption are increased 60% and 79% respect-ively, in patients with moderate renal im-pairment.	fold in cirrhotic patients, and peak values varied 47-fold.	disease.	sufficiency.

V. HMG-CoA Reductase Inhibitor Drug Interactions

Table 5. HMG-CoA Reductase Inhibitor Drug Interactions

Precipitant drug	Object drug		Description
Amiodarone	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Amiodarone may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). If coadministration cannot be avoided, use the lowest possible H MG-CoA reductase inhibitor dose.
Antacids	HMG-CoA reductase inhibitors Rosuvastatin Atorvastatin	↓	Coadministration with aluminum hydroxide/magnesium hydroxide suspension decreased atorvastatin levels by approximately 35%; LDL-C reduction was not altered. Coadministration of rosuvastatin and an aluminum/magnesium combination antacid decreased rosuvastatin levels by 54%. Administer antacids at least 2 hours after rosuvastatin.
Azole antifungals (eg, fluconazole, itraconazole, ketoconazole)	HMG-CoA reductase inhibitors	↑	Azole antifungal agents may inhibit the metabolism of HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). Itraconazole is contraindicated with HMG-CoA reductase inhibitors metabolized by CYP3A4. If coadministration of other agents cannot be avoided, consider suspending the dose of the HMG-CoA reductase inhibitor during the course of therapy. Pravastatin and rosuvastatin levels are affected the least.
Bile acid sequestrants (eg, cholestyramine, colestipol)	H MG-CoA reductase inhibitors Atorvastatin Pravastatin Fluvastatin	↓	The H MG-CoA reductase inhibitor may adsorb to the bile acid sequestrant, reducing the GI absorption of the HMG-CoA reductase inhibitor. Administer pravastatin I hour before or4 hours after bile acid sequestrants. Administer fluvastatin at least 2 hours after a bile acid sequestrant. Plasma levels of atorvastatin decreased approximately 25% with

Precipitant drug	Object drug		Description
			coadministration with colestipol; however, LDL-C reduction was greater when atorvastatin and colestipol were coadministered than when either drug was given alone.
Bosentan	H MG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↓	Bosentan may induce the metabolism (CYP3A4) of certain H MG-CoA reductase inhibitors, decreasing the therapeutic effect. Monitor closely and adjust dosage as needed.
Carbamazepine	H MG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↓	Carbamazepine may induce the metabolism (CYP3A4) of certain H MG-CoA reductase inhibitors, decreasing the therapeutic effect. Monitor closely and adjust dosage as needed.
Cilostazole	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Cilostazole may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). Monitor closely and adjust dosage as needed.
Cisapride	H MG-CoA reductase inhibitors Simvastatin	↑↓	Coadministration may decrease simvastatin levels, and cisapride levels may be elevated.
HMG-CoA reductase inhibitors	Cisapride		
Colchicine	HMG-CoA reductase inhibitors	↑	Coadministration may increase the risk of myopathy or rhabdomyolysis. If coadministration cannot be avoided, then use with caution and closely monitor CK.
HMG-CoA reductase inhibitors	Colchicine		
Cyclosporine	HMG-CoA reductase inhibitors	↑	Coadministration may increase HMG-CoA reductase inhibitor plasma levels and increase the risk of myopathy or rhabdomyolysis. If coadministration cannot be avoided, consider decreasing HMG-CoA reductase inhibitor dose and monitor closely. Lovastatin ER should not be coadministered with cyclosporine; however, reduced dosage of immediate-release lovastatin may be considered. Coadministration with pitavastatin is contraindicated.

Precipitant drug	Object drug		Description
Danazol	HMG-CoA reductase inhibitors Lovastatin Simvastatin	↑	Coadministration may cause myopathy or rhabdomyolysis. If coadministration cannot be avoided, consider decreasing the HMG-CoA reductase inhibitor dose and monitor closely.
Diltiazem	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Diltiazem may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy).
Fibric acid derivatives (ie, fenofibrate, gemfibrozil)	HMG-CoA reductase inhibitors	↑	Severe myopathy or rhabdomyolysis may occur. Avoid concurrent use if possible. If used, consider a reduced dosage of the HMG-CoA reductase inhibitor.
HMG-CoA reductase inhibitors	Fibric acid derivatives (ie, fenofibrate, gemfibrozil)		
Glyburide	HMG-CoA reductase inhibitors Fluvastatin	↑	Coadministration increased glyburide Cmax, AUC, and half-life approximately 50%, 69%, and 121%, respectively. Coadministration also led to an increase in fluvastatin Cmax and AUC by 44% and 51%, respectively. Monitor patients.
HMG-CoA reductase inhibitors Fluvastatin	Glyburide		
Histamine H2 antagonists (ie, cimetidine, ranitidine)	HMG-CoA reductase inhibitors Fluvastatin	↑	Coadministration of fluvastatin with cimetidine and ranitidine resulted in a significant increase in fluvastatin Cmax and AUC by 44% and 51%, respectively. Monitor patients.
Hydantoins (eg, phenytoin)	HMG-CoA reductase inhibitors Atorvastatin Fluvastatin Simvastatin	↑↓	Coadministration may result in decreased plasma levels of certain HMG-CoA reductase inhibitors, producing a decrease in therapeutic effect. Coadministration of fluvastatin and phenytoin increased the levels of both drugs.
HMG-CoA reductase inhibitors Fluvastatin	Hydantoins (eg, phenytoin)		
Imatinib	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Imatinib may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy).
Isradipine	HMG-CoA reductase inhibitors Lovastatin	↓	Isradipine may increase clearance of lovastatin and its metabolites by increasing hepatic blood flow. Monitor the clinical response and adjust the lovastatin dosage as necessary.
Macrolides Clarithromycin Erythromycin	HMG-CoA reductase inhibitors	↑	Certain macrolides may inhibit the metabolism of HMG-CoA reductase inhibitors metabolized by CYP3A4. Coadministration increases the risk of severe myopathy or rhabdomyolysis. If

Precipitant drug	Object drug		Description
			coadministration is unavoidable, suspend therapy with an HMG-CoA reductase inhibitor during the course of macrolide therapy. Do not exceed a dosage of **pitavastatin** 1 mg once daily during coadministration.
Nefazodone	HMG-CoA reductase inhibitors	↑	Nefazodone may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). Avoid use if possible.
Niacin (nicotinic acid)	HMG-CoA reductase inhibitors	↑	Coadministration of HMG-CoA reductase inhibitors with niacin (dosages of at least 1 g/day) increases the risk of severe myopathy or rhabdomyolysis. If coadministration cannot be avoided, use the lowest possible HMG-CoA reductase inhibitor dose.
HMG-CoA reductase inhibitors	Niacin (nicotinic acid)		
NNRTIs (eg, delavirdine, efavirenz, nevirapine)	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Pravastatin Simvastatin	↑↓	Delavirdine may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). However, efavirenz and nevirapine may induce CYP3A4 and reduce HMG-CoA reductase inhibitor levels.
Omeprazole	HMG-CoA reductase inhibitors Fluvastatin	↑	Coadministration of fluvastatin with omeprazole resulted in a significant increase in fluvastatin Cmax (50%) and AUC (24% to 33%), with an 18% to 23% decrease in plasma clearance.
Propranolol	HMG-CoA reductase inhibitors Simvastatin	↔	Coadministration resulted in a significant decrease in simvastatin Cmax, but no change in AUC. No dosage adjustment is needed.
Protease inhibitors (eg, nelfinavir, ritonavir)	HMG-CoA reductase inhibitors	↑↓	Concomitant use may result in elevated plasma levels of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). Darunavir or nelfinavir is contraindicated in patients taking lovastatin or simvastatin; avoid coadministration with ritonavir or atazanavir. However, concomitant use of a protease inhibitor with pravastatin may decrease pravastatin plasma levels, possibly decreasing efficacy. Avoid use if possible.
Quinine	HMG-CoA reductase inhibitors Atorvastatin	↑	Quinine may inhibit the metabolism (CYP3A4) of atorvastatin, increasing the risk of toxicity (eg, myopathy).
Rifamycins (eg, rifampin)	HMG-CoA reductase inhibitors Atorvastatin Fluvastatin Pitavastatin Pravastatin	↑↓	Coadministration may reduce levels of certain HMG-CoA reductase inhibitors. However, pravastatin and pitavastatin levels may be increased in some patients. Do not exceed a dosage of pitavastatin 2 mg once daily during coadministration
St. John's wort	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↓	St. John's wort may induce the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, decreasing therapeutic effect.

Precipitant drug	Object drug		Description
Telithromycin	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Telithromycin may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy).
Verapamil	HMG-CoA reductase inhibitors Atorvastatin Lovastatin Simvastatin	↑	Verapamil may inhibit the metabolism (CYP3A4) of certain HMG-CoA reductase inhibitors, increasing the risk of toxicity (eg, myopathy). If coadministration cannot be avoided, consider decreasing the HMG-CoA reductase inhibitor dose and monitor closely. Atorvastatin may also increase the levels of verapamil.
HMG-CoA reductase inhibitors Atorvastatin	Verapamil		
HMG-CoA reductase inhibitors Atorvastatin	Benzodiazepines (ie, midazolam)	↑	Atorvastatin may decrease the oxidative metabolism (CYP3A4) of certain benzodiazepines. The effects of the benzodiazepines may be increased and prolonged.
HMG-CoA reductase inhibitors Atorvastatin Fluvastatin Lovastatin Simvastatin	Clopidogrel	↓	Data for this interaction are conflicting. Certain HMG-CoA reductase inhibitors may interfere with clopidogrel platelet inhibition. One case of rhabdomyolysis has been reported. No special precautions are needed based on available data.
HMG-CoA reductase inhibitors Atorvastatin Rosuvastatin	Contraceptives, hormonal	↑	Coadministration with atorvastatin increased the AUC for norethindrone and ethinyl estradiol by approximately 30% and 20%, respectively. Coadministration with rosuvastatin increased the AUC for norgestrel and ethinyl estradiol by approximately 34% and 26%, respectively.
HMG-CoA reductase inhibitors Fluvastatin	Diclofenac	↑	Coadministration increased the mean diclofenac Cmax and AUC by 60% and 25%, respectively.
HMG-CoA reductase inhibitors Atorvastatin Fluvastatin Rosuvastatin Simvastatin	Digoxin	↑	Coadministration may increase digoxin plasma concentrations. Monitor digoxin levels and adjust the dosage as needed.
HMG-CoA reductase inhibitors Fluvastatin Lovastatin Pitavastatin Rosuvastatin Simvastatin	Warfarin	↑	The anticoagulant effect of warfarin may increase. Bleeding also has been reported in a few patients. Monitor anticoagulation parameters when starting, stopping, or adjusting the HMG-CoA reductase inhibitor dosage.

VI. Comparative Adverse Effects of HMG-CoA Reductase Inhibitors

Statins are generally well tolerated with the most common side effects being abdominal pain, constipation, flatulence, and headache. More serious but rare side effects of statins include increases in liver enzymes and myopathy accompanied by elevations in creatine kinase, which can progress to rhabdomyolysis and acute renal failure. Routine liver function monitoring is recommended with each statin, with only slight variations in this monitoring parameter existing between statins. Increases in hepatic transaminases (> 3x ULN) have been reported with statins (0.5%-2.0%) and appear to be dose-dependent (risk increases as the statin dose increases). Elevations in hepatic transaminases frequently reverse with a reduction in dose or suspension of therapy. Upon re-challenge or initiation of another statin, elevations in liver enzymes do not often occur. Myositis (defined as elevated creatine kinase – generally > 10 times the ULN – plus symptomatic muscle aches/weakness) has also been reported with statins (0.1-0.5%), as has rhabdomyolysis when statins are used as monotherapy (0.04%-0.2%).

With regard to more minor adverse reactions, no clear differences seem to exist between the drugs in this class. Patients who do not tolerate one statin generally may tolerate another (tolerability differences between statins do exist for unknown reasons).

Table 6. Adverse Reactions (%) Reported with the HMG-CoA Reductase Inhibitors

Adverse Effects	Atorvastatin	Fluvastatin	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Cardiovascular							
Angina pectoris	< 2%	-	-	-	3.1%	-	-
Atrial fibrillation	-	-	-	-	-	-	5.7%
Hypertension	< 2%	-	-	-	-	-	-
CNS							
Asthenia	≤ 3.8%	-	1.2% to 3%	-	PM	2.7%	√
Depression	< 2%	√	-	-	1%	-	PM
Dizziness	≥ 2%	√	0.5% to 2%	-	1% to 2.2%	4%	PM
Headache	2.5% to 16.7%	4.7% to 8.9%	2.1% to 7%	√	1.7% to 1.9%	5.5% to 6.4%	7.4%
Insomnia	≥ 2%	0.8% to 2.7%	0.5% to 1%	-	< 1%	-	4%
Paresthesia	< 2%	√	0.5% to 1%	-	< 1%	-	PM
Vertigo	-	√	√	-	< 1%	-	4.5%
Dermatologic							
Alopecia	< 2%	√	0.5% to 1%	-	< 1%	-	PM
Eczema	< 2%	-	-	-	-	-	4.5%
Pruritus	< 2%	√	0.5% to 1%	-	< 1%	√	PM
Rash	1.1% to 3.9%	-	0.8% to 1.3%	-	1.3% to 2.1%	√	√
GI							
Abdominal pain/cramps	≤ 3.8%	3.7% to 4.9%	2% to 2.5%	-	2% to 2.4%	2.4%	7.3%
Acid regurgitation	-	-	0.5% to 1%	-	-	-	-
Constipation	≤ 2.5%	-	2% to 3.5%	3.6%	1.2% to 2.4%	2.4%	6.6%

Adverse Effects	Atorvastatin	Fluvastatin	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Diarrhea	≤ 5.3%	3.3% to 4.9%	2.2% to 3%	2.6%	2%	-	√
Dry mouth	< 2%	-	0.5% to 1%	-	-	-	-
Dysgeusia	< 2%	-	0.8%	-	-	-	-
Dyspepsia	1.3% to 2.8%	3.5% to 7.9%	1% to 1.6%	-	3.5%	-	√
Flatulence	1.1% to 2.8%	1.4% to 2.6%	3.7% to 4.5%	-	1.2% to 2.7%	-	√
Gastroenteritis	< 2%	-	-	-	-	≥ 2%	4.9%
Heartburn	-	-	1.6%	-	2%	-	-
Nausea	≥ 2%	2.5% to 3.2%	1.9% to 2.5%	-	1.6% to 2.9%	3.4%	5.4%
Vomiting	< 2%	√	0.5% to 1%	-	1.6% to 2.9%	-	PM
GU							
Albuminuria	≥ 2%	-	-	-	-	-	-
Hematuria	≥ 2%	-	-	-	-	√	-
Urinary abnormality	-	-	-	-	0.7% to 1%	-	-
Urinary tract infection	≥ 2%	1.6% to 2.7%	2% to 3%	-	-	-	3.2%
Lab test abnormalities							
ALT > 3 X ULN	0.2% to 2.3%	0.2% to 4.9%	1.9%	-	≤ 1.2%	2.2%	1%
Elevated CPK	< 2%	√	√	√	√	2.6%	√
Musculoskeletal							
Arthralgia	≤ 5.1%	√	0.5% to 5%	√	PM	10.1%	PM
Arthritis	≥ 2%	1.3% to 2.1%	-	-	√	PM	-
Arthropathy	-	3.2%	-	-	-	-	-
Back pain	≤ 3.8%	-	5%	3.9%	-	-	-
Leg pain	< 2%	-	0.5% to 1%	-	-	-	-
Localized pain	-	-	0.5% to 1%	-	1.4%	-	-
Muscle cramps/pain	-	√	0.6% to 1.1%	-	2% to 6%	12.7%	PM
Myalgia	≤ 5.6%	3.8% to 5%	1.8% to 3%	3.1%	0.6% to 1.4%	2.8%	3.7%
Myopathy	√	√	√	-	PM	√	0.02% to 0.53%
Rhabdomyolysis	PM	√	√	-	PM	√	√
Shoulder pain	-	-	0.5% to 1%	-	-	-	-
Ophthalmic							
Blurred vision	-	-	0.9% to 1.2%	-	-	-	-
Eye irritation	-	-	0.5% to 1%	-	-	-	-
Visual disturbance	-	-	-	-	1.6%	-	-
Respiratory							
Bronchitis	≥ 2%	1.8% to 2.6%	-	-	-	-	6.6%
Cough	-	-	-	-	0.1% to 1%	-	-
Dyspnea	< 2%	-	-	-	1.6%	-	-
Pharyngitis	≤ 2.5%	-	-	-	-	-	-
Rhinitis	≥ 2%	-	-	-	0.1%	-	-
Sinusitis	≤ 6.4%	2.6% to 3.5%	4% to 6%	-	-	-	2.3%
Upper respiratory tract infection	-	-	-	-	1.3%	-	9%
Miscellaneous							
Accidental trauma	≤ 4.2%	4.2% to 5.1%	4% to 6%	-	-	-	-

Adverse Effects	Atorvastatin	Fluvastatin	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin	Simvastatin
Allergy/hyper-sensitivity	≤ 2.8%	1% to 2.3%	-	√	< 1%	√	PM
Chest pain	≥ 2%	-	0.5% to 1%	-	0.1% to 2.6%	-	-
Diabetes mellitus	-	-	-	-	-	-	4.2%
Edema/Swelling	< 2%	-	-	-	-	-	2.7%
Fatigue	PM	1.6% to 2.7%	-	-	1.9% to 3.4%	-	-
Flu syndrome	≤ 3.2%	5.1% to 7.1%	5%	-	-	-	-
Infection	2.8% to 10.3%	-	11% to 16%	-	-	-	-
Pain	-	-	3% to 5%	-	1.4%	≥ 2%	-
Peripheral edema	≥ 2%	-	-	-	-	≥ 2%	-

√ = reported but no evidence given
PM = postmarketing

VII. Dosing and Administration of HMG-CoA Reductase Inhibitors

Table 7. HMG-CoA Reductase Inhibitor Dosing & Administration

	Initial Dose	Dosing Range	Maximum Dose
Atorvastatin	10mg QD	10-80mg QD	80mg QD
Fluvastatin/ Fluvastatin XL	20mg QD 80mg QD (ER)	20-80mg QD	80mg QD
Lovastatin/ Lovastatin ER	20mg QD	10-80mg QD 10-60mg QD (ER)	80mg QD 60mg QD (ER)
Pitavastatin	2mg QD	1-4mg QD	4mg QD
Pravastatin	40mg QD	10-80mg QD	80mg QD
Rosuvastatin	10mg QD	5-40mg QD	40mg QD
Simvastatin	20mg QD	5-80mg QD	80mg QD

VIII. Conclusion

When clinically evaluating the HMG CoA reductase inhibitor class, it is important to look closely at safety and patient outcomes data. However, because the NCEP ATP III guidelines recommend such strict control of LDL-C, the efficacy and LDL-C lowering capacity must also be considered.

As demonstrated in clinical studies, no clear differences seem to exist between the statins in terms of safety. All of the drugs in this class have beneficial effects on coronary heart disease (CHD) outcomes. Atorvastatin, fluvastatin, pravastatin, and simvastatin have also been shown to reduce cardiovascular events in patients with clinically evident CHD (secondary prevention). In addition, fluvastatin, lovastatin, pravastatin, and rosuvastatin have been shown to slow the progression of coronary atherosclerosis in patients with CHD. Studies have demonstrated that statins (atorvastatin, pravastatin, rosuvastatin, and simvastatin) also decrease the risk of stroke. Studies have also demonstrated that combination products are safe, effective and show

therapeutic benefit but offer no clinical advantage over the concurrent administration of the individual components.

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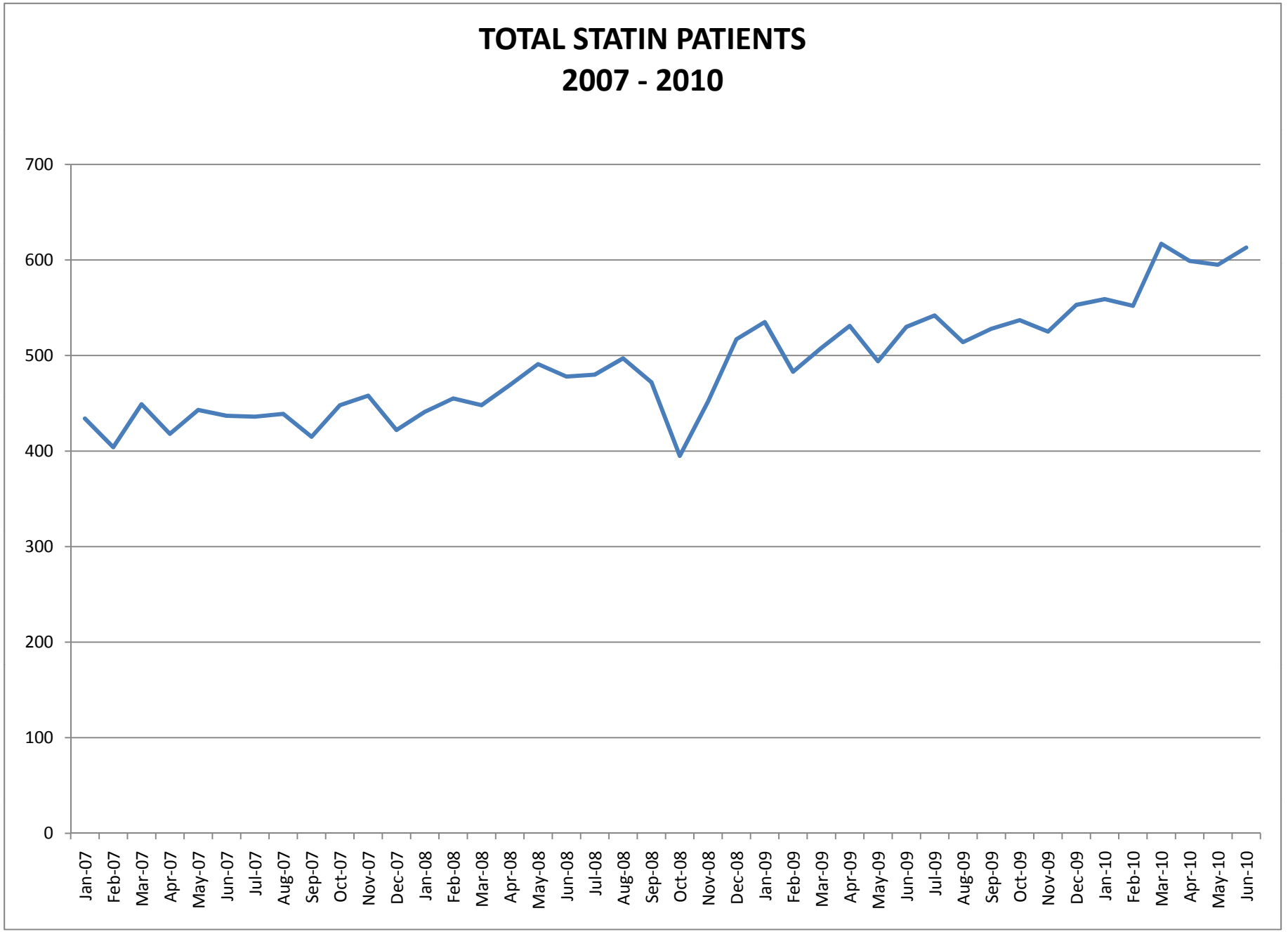
SD Medicaid
Statin Utilization
July 2009 - June 2010

Label Name	Rx Num	Total Reimb Amt	Cost per Script
ADVICOR 500 MG-20 MG TABLET	3	$295.62	$98.54
CADUET 10 MG-10 MG TABLET	16	$1,900.35	$118.77
CADUET 10 MG-20 MG TABLET	60	$9,686.44	$161.44
CADUET 10 MG-40 MG TABLET	1	$166.87	$166.87
CADUET 10 MG-80 MG TABLET	21	$3,380.70	$160.99
CADUET 5 MG-10 MG TABLET	14	$1,658.67	$118.48
CADUET 5 MG-20 MG TABLET	37	$5,977.60	$161.56
CADUET 5 MG-40 MG TABLET	24	$3,885.69	$161.90
CRESTOR 10 MG TABLET	201	$17,972.69	$89.42
CRESTOR 20 MG TABLET	392	$29,523.88	$75.32
CRESTOR 40 MG TABLET	340	$30,127.19	$88.61
CRESTOR 5 MG TABLET	50	$5,268.59	$105.37
LESCOL 40 MG CAPSULE	12	$1,040.35	$86.70
LESCOL XL 80 MG TABLET	21	$2,326.33	$110.78
LIPITOR 10 MG TABLET	175	$15,214.39	$86.94
LIPITOR 20 MG TABLET	677	$55,976.38	$82.68
LIPITOR 40 MG TABLET	585	$45,818.34	$78.32
LIPITOR 80 MG TABLET	508	$43,063.43	$84.77
LOVASTATIN 10 MG TABLET	55	$518.30	$9.42
LOVASTATIN 20 MG TABLET	195	$1,784.36	$9.15
LOVASTATIN 40 MG TABLET	118	$1,772.42	$15.02
PRAVASTATIN SODIUM 10 MG TAB	16	$134.97	$8.44
PRAVASTATIN SODIUM 20 MG TAB	49	$531.84	$10.85
PRAVASTATIN SODIUM 40 MG TAB	249	$2,590.39	$10.40
PRAVASTATIN SODIUM 80 MG TAB	33	$578.10	$17.52
SIMCOR 1,000-20 MG TABLET	12	$1,446.97	$120.58
SIMCOR 500-20 MG TABLET	3	$209.61	$69.87
SIMVASTATIN 10 MG TABLET	76	$828.66	$10.90
SIMVASTATIN 20 MG TABLET	553	$4,997.27	$9.04
SIMVASTATIN 40 MG TABLET	1306	$11,328.38	$8.67
SIMVASTATIN 5 MG TABLET	3	$27.23	$9.08
SIMVASTATIN 80 MG TABLET	1278	$11,903.06	$9.31
VYTORIN 10-10 MG TABLET	5	$537.27	$107.45
VYTORIN 10-20 MG TABLET	165	$18,088.06	$109.62
VYTORIN 10-40 MG TABLET	119	$12,971.06	$109.00
VYTORIN 10-80 MG TABLET	31	$3,237.56	$104.44
Totals 1,141 recipients	**7403**	**$346,769.02**	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300
200
100
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Mar-07
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Jun-07
Jul-07
Aug-07
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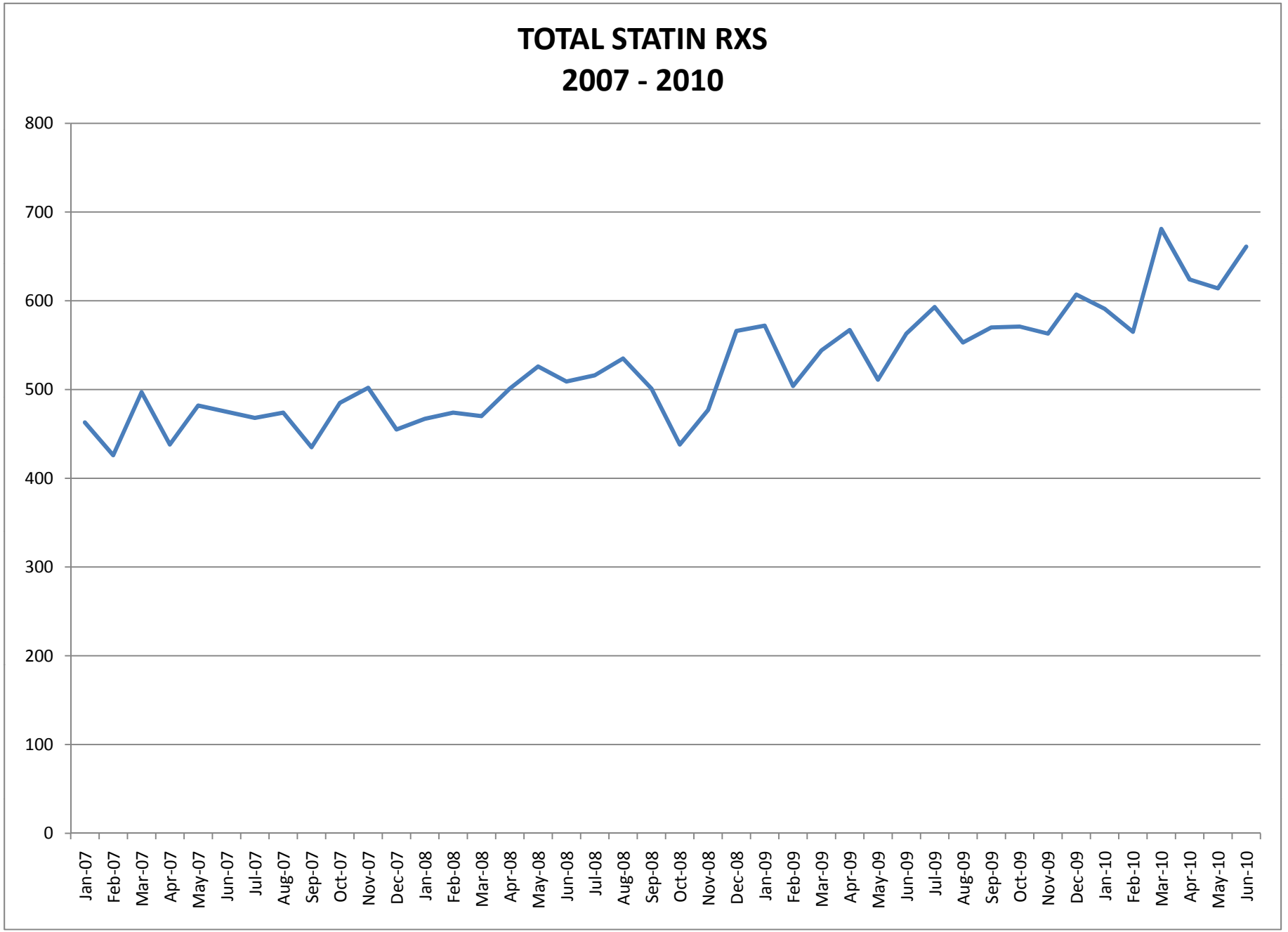
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400
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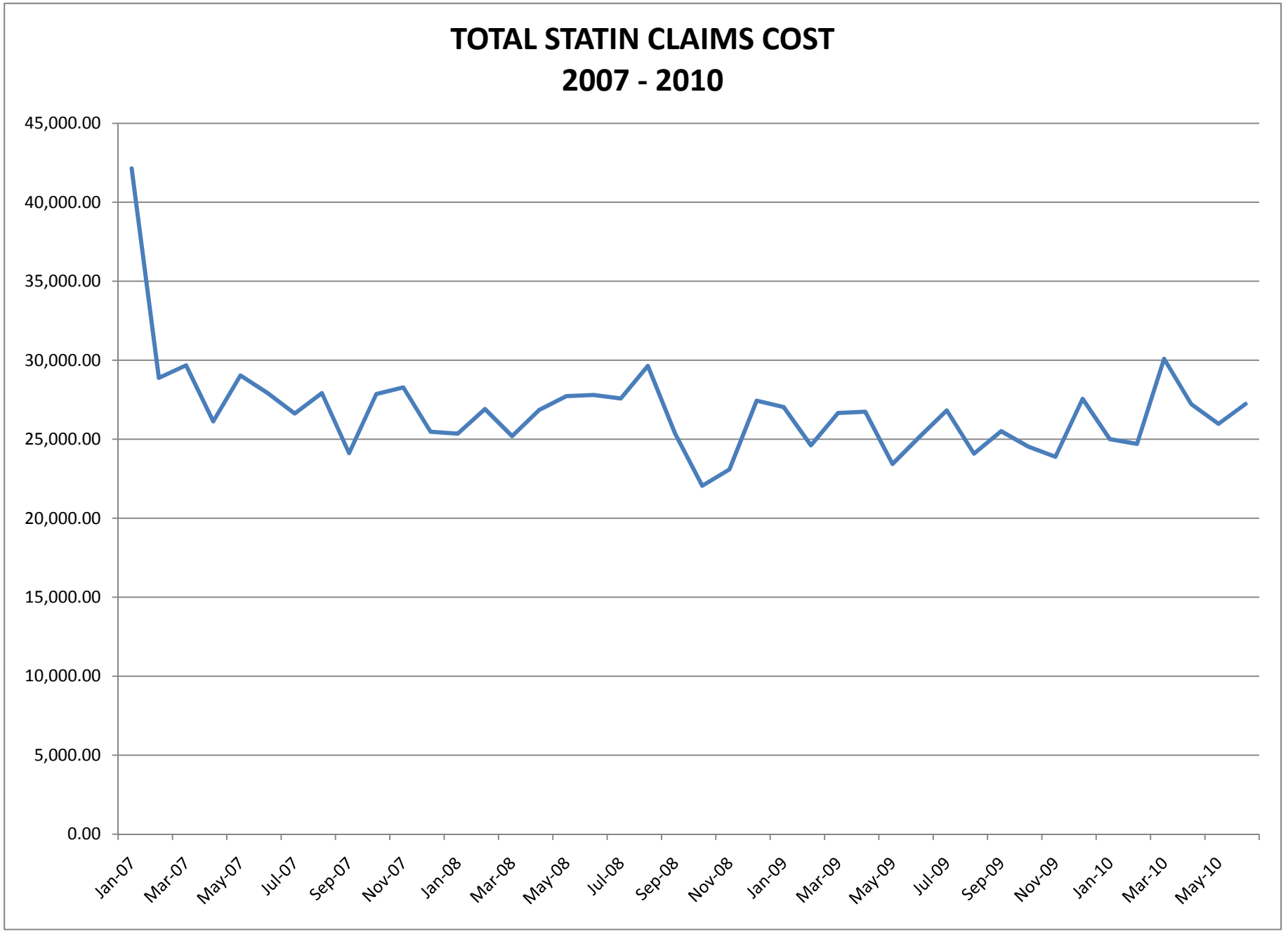
TOTAL STATIN CLAIMS COST
2007 - 2010
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30,000.00
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May-07
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Jul-08
Sep-08
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Jan-09
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May-09
Jul-09
Sep-09
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May-10

South Dakota Medicaid
P&T Committee Meeting
Soma 250®

I. Overview

Carisoprodol 350mg is a skeletal muscle relaxant that has been available in the United States for almost 50 years. In September 2007, Soma® 250mg (carisoprodol) was approved by the FDA. Carisoprodol is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions.

II. Pharmacology

The mechanism of action of carisoprodol in relieving discomfort associated with acute painful musculoskeletal conditions has not been clearly identified. In animal studies, muscle relaxation induced by carisoprodol is associated with altered interneuronal activity in the spinal cord and in the descending reticular formation of the brain.

III. Pharmacokinetics

Pharmacokinetic Parameters of Carisoprodol 250mg and 350mg		
	250mg Carisoprodol	**350mg Carisoprodol**
Cmax	1.2 ± 0.5	1.8 ± 1.0
AUC	4.5 ± 3.1	7.0 ± 5.0
Tmax	1.5 ± 0.8	1.7 ± 0.8
$T_{½}$	1.7 ± 0.5	2.0 ± 0.5

Metabolism: The major pathway of carisoprodol metabolism is via the liver by cytochrome enzyme CYP2C19 to form meprobamate.

Elimination: Carisoprodol is eliminated by both renal and non-renal routes with a terminal elimination half-life of approximately 2 hours. The half-life of meprobamate is approximately 10 hours.

IV. Warnings/Precautions

Sedation: Carisoprodol may have sedative properties and may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery.

Drug Dependence, Withdrawal, and Abuse: In the postmarketing experience with carisoprodol, cases of dependence, withdrawal and abuse have been reported with prolonged use. Most cases of dependence, withdrawal and abuse occurred in patients who have had a history of addiction or who used carisoprodol in combination with other drugs with abuse potential. Withdrawal symptoms have been reported following abrupt cessation after prolonged use. To reduce the chance of carisoprodol dependence, withdrawal, and abuse, carisoprodol should be used with caution in addiction-prone patients and in patients taking other CNS depressants including alcohol, and carisoprodol should not be used more than two to three weeks for the relief of acute musculoskeletal discomfort.

Seizures: There have been postmarketing reports of seizures in patients who received carisoprodol. Most of these cases have occurred in the setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol).

V. Contraindications:

Carisoprodol is contraindicated in patients with a history of acute intermittent porphyria or a hypersensitivity reaction to a carbamate such as meprobamate.

VI. Drug Interactions

CNS Depressants: The sedative effects of carisoprodol and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive. Therefore caution should be exercised with patients who take more than one of these CNS depressants, simultaneously. Concomitant use of carisoprodol and meprobamate, a metabolite of carisoprodol, is not recommended.

CYP2C19 Inhibitors and Inducers: Carisoprodol is metabolized in the liver by CYP2C19 to form meprobamate. Co-administration of CYP2C19 inhibitors, such as omeprazole or fluvoxamine, with carisoprodol could result in increased exposure of carisoprodol and decreased exposure of meprobamate. Co-administration of CYP2C19 inducers, such as rifampin or St. John's Wort, with carisoprodol could result in decreased exposure of carisoprodol and increased exposure of meprobamate. Low dose aspirin also showed induction effect on CYP2C19. The full pharmacological impact of these potential alterations of exposures in terms of either efficacy or safety of carisoprodol is unknown.

VII. Adverse Drug Events

Patients with Adverse Reactions in Controlled Studies			
Adverse Reaction	**Placebo (%)**	**Soma 250mg (%)**	**Soma 350mg (%)**
Drowsiness	6	13	17
Dizziness	2	8	7
Headache	2	5	3

VIII. Dosing and Administration

The recommended dose of carisoprodol is 250mg to 350mg three times a day and at bedtime. The recommended maximum duration of carisoprodol use is up to two or three weeks.

IX. Cost and Current Carisoprodol Utilization

Carisoprodol 250mg costs approximately $3.02 per tablet (AWP) compared to carisoprodol generic 350mg, which costs approximately $.08 per tablet (AWP).

SD Medicaid Carisoprodol Utilization July 2009 – June 2010			
Label Name	**Rx Num**	**Total Reimb Amt**	**Cost per Script**
Soma 250	24	$3,238.13	$134.92
Carisoprodol 350	980	$9,754.75	$9.95

X. Conclusion

Carisoprodol 250mg seems as effective as carisoprodol 350mg with better tolerability for some patients. Both strengths are given four times a day and have similar modest effects for acute low back pain. The incidence of drowsiness with carisoprodol 250mg is 13%, compared to 17% with the 350mg strength. Without a clearly superior agent, cost becomes the significant consideration when choosing which strength of carisoprodol to use. Neither formulation should be used first-line due to abuse potential, addiction and psychomotor impairment.

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South Dakota Medicaid
P&T Committee Meeting
Multaq® Review

I. Overview

MULTAQ is an antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted.

II. Pharmacology

The mechanism of action of dronedarone is unknown. Dronedarone has antiarrhythmic properties belonging to all four Vaughan-Williams classes, but the contribution of each of these activities to the clinical effect is unknown.

III. Pharmacokinetics

Dronedarone is extensively metabolized and has low systemic bioavailability; its bioavailability is increased by meals. Its elimination half life is 13‑19 hours.

Absorption
Because of presystemic first pass metabolism the absolute bioavailability of dronedarone without food is low, about 4%. It increases to approximately 15% when dronedarone is administered with a high fat meal. After oral administration in fed conditions, peak plasma concentrations of dronedarone and the main circulating active metabolite (N-debutyl metabolite) are reached within 3 to 6 hours. After repeated administration of 400 mg twice daily, steady state is reached within 4 to 8 days of treatment and the mean accumulation ratio for dronedarone ranges from 2.6 to 4.5. The steady state Cmax and exposure of the main N-debutyl metabolite is similar to that of the parent compound. The pharmacokinetics of dronedarone and its N-debutyl metabolite both deviate moderately from dose proportionality: a 2-fold increase in dose results in an approximate 2.5- to 3.0-fold increase with respect to Cmax and AUC.

Distribution
The *in vitro* plasma protein binding of dronedarone and its N-debutyl metabolite is >98 % and not saturable. Both compounds bind mainly to albumin. After intravenous (IV) administration the volume of distribution at steady state is about 1400 L.

Metabolism
Dronedarone is extensively metabolized, mainly by CYP 3A. The initial metabolic pathway includes N-debutylation to form the active N-debutyl metabolite, oxidative

deamination to form the inactive propanoic acid metabolite, and direct oxidation. The metabolites undergo further metabolism to yield over 30 uncharacterized metabolites. The N-debutyl metabolite exhibits pharmacodynamic activity but is 1/10 to 1/3 as potent as dronedarone.

Excretion/Elimination
In a mass balance study with orally administered dronedarone (14C-labeled) approximately 6% of the labeled dose was excreted in urine, mainly as metabolites (no unchanged compound excreted in urine), and 84% was excreted in feces, mainly as metabolites. Dronedarone and its N-debutyl active metabolite accounted for less than 15% of the resultant radioactivity in the plasma.

After IV administration the plasma clearance of dronedarone ranges from 130 to 150 L/h. The elimination half-life of dronedarone ranges from 13 to 19 hours.

IV. Warnings/Precautions

Patients with New or Worsening Heart Failure during Treatment
Advise patients to consult a physician if they develop signs or symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. There are limited data available for AF/AFL patients who develop worsening heart failure during treatment with MULTAQ. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

Hypokalemia and Hypomagnesemia with Potassium-Depleting Diuretics
Hypokalemia or hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be within the normal range prior to administration of MULTAQ and maintained in the normal range during administration of MULTAQ.

QT Interval Prolongation
Dronedarone induces a moderate (average of about 10 ms but much greater effects have been observed) QTc (Bazett) prolongation. If the QTc Bazett interval is ≥500 ms, MULTAQ should be stopped.

Increase in Creatinine after Treatment Initiation
Serum creatinine levels increase by about 0.1 mg/dL following dronedarone treatment initiation. The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation. If an increase in serum creatinine occurs and plateaus, this increased value should be used as the patient's new baseline. The change in creatinine levels has been shown to be the result of an inhibition of creatinine's tubular secretion, with no effect upon the glomerular filtration rate.

Women of Childbearing Potential
Premenopausal women who have not undergone a hysterectomy or oophorectomy must use effective contraception while using MULTAQ. Dronedarone caused fetal harm in

animal studies at doses equivalent to recommended human doses. Women of childbearing potential should be counseled regarding appropriate contraceptive choices taking into consideration their underlying medical conditions and lifestyle preferences.

V. Drug Interactions

Dronedarone is metabolized primarily by CYP 3A and is a moderate inhibitor of CYP 3A and CYP 2D6. Dronedarone's blood levels can therefore be affected by inhibitors and inducers of CYP 3A, and dronedarone can interact with drugs that are substrates of CYP 3A and CYP 2D6. Dronedarone has the potential to inhibit P-glycoprotein (P-gP) transport.

A. Pharmacodynamic Interactions

Drugs prolonging the QT interval (inducing Torsade de Pointes)
Co-administration of drugs prolonging the QT interval (such as certain phenothiazines, tricyclic antidepressants, certain macrolide antibiotics, and Class I and III antiarrhythmics) is contraindicated because of the potential risk of Torsade de Pointes-type ventricular tachycardia.

Digoxin
Digoxin can potentiate the electrophysiologic effects of dronedarone (such as decreased AV-node conduction). In clinical trials, increased levels of digoxin were observed when dronedarone was co-administered with digoxin. Gastrointestinal disorders were also increased. Because of the pharmacokinetic interaction and possible pharmacodynamic interaction, reconsider the need for digoxin therapy. If digoxin treatment is continued, halve the dose of digoxin, monitor serum levels closely, and observe for toxicity.

Calcium channel blockers
Calcium channel blockers with depressant effects on the sinus and AV nodes could potentiate dronedarone's effects on conduction. Give low doses of calcium channel blockers initially and increase only after ECG verification of good tolerability.

Beta-blockers
In clinical trials, bradycardia was more frequently observed when dronedarone was given in combination with beta-blockers. Give low dose of beta-blockers initially, and increase only after ECG verification of good tolerability.

B. Effects of Other Drugs on Dronedarone

Ketoconazole and other potent CYP 3A inhibitors
Repeated doses of ketoconazole, a strong CYP 3A inhibitor, resulted in a 17-fold increase in dronedarone exposure and a 9-fold increase in Cmax. Concomitant use of ketoconazole as well as other potent CYP 3A inhibitors such as itraconazole, voriconazole, ritonavir, clarithromycin, and nefazodone is contraindicated.

Grapefruit juice
Grapefruit juice, a moderate inhibitor of CYP 3A, resulted in a 3-fold increase in dronedarone exposure and a 2.5-fold increase in Cmax. Therefore, patients should avoid grapefruit juice beverages while taking MULTAQ.
Rifampin and other CYP 3A inducers
Rifampin decreased dronedarone exposure by 80%. Avoid rifampin or other CYP 3A inducers such as phenobarbital, carbamazepine, phenytoin, and St John's wort with dronedarone because they decrease its exposure significantly.

Calcium channel blockers
Verapamil and diltiazem are moderate CYP 3A inhibitors and increase dronedarone exposure by approximately 1.4-to 1.7-fold.

C. Effects of Dronedarone on Other Drugs

Statins
Dronedarone increased simvastatin/simvastatin acid exposure by 4- and 2-fold, respectively. Because of multiple mechanisms of interaction with statins (CYPs and transporters), follow statin label recommendations for use with CYP 3A and P-gP inhibitors such as dronedarone.

Calcium channel blockers
Dronedarone increases calcium channel blocker (verapamil, diltiazem or nifedipine) exposure by 1.4- to 1.5-fold.

Sirolimus, tacrolimus, and other CYP3A substrates with narrow therapeutic range
Dronedarone can increase plasma concentrations of tacrolimus, sirolimus, and other CYP 3A substrates with a narrow therapeutic range when given orally. Monitor plasma concentrations and adjust dosage appropriately.

Beta-blockers and other CYP 2D6 substrates
Dronedarone increased propranolol exposure by approximately 1.3-fold following single dose administration. Dronedarone increased metoprolol exposure by 1.6-fold following multiple dose administration. Other CYP 2D6 substrates, including other beta-blockers, tricyclic antidepressants, and selective serotonin reuptake inhibitors (SSRIs) may have increased exposure upon co-administration with dronedarone.

Digoxin and P-glycoprotein substrates
Dronedarone increased digoxin exposure by 2.5-fold by inhibiting the P-gP transporter. Other P-gP substrates are expected to have increased exposure when coadministered with dronedarone.

Warfarin and losartan (CYP 2C9 substrates)
In healthy subjects, dronedarone at a dose of 600 mg twice daily increased S-warfarin exposure by 1.2-fold with no change in R-warfarin and with no clinically significant increase in INR. In clinical trials in patients with AF/AFL, there was no observed excess

risk of bleeding compared to placebo when dronedarone was co-administered with oral anticoagulants. Monitor INR per the warfarin label.
No interaction was observed between dronedarone and losartan.

VI. Adverse Events

Table 1: Adverse Drug Reactions that Occurred in at Least 1% of Patients and Were More Frequent than Placebo

	Placebo (N=2875)	**Dronedarone 400 mg twice daily (N=3282)**
Gastrointestinal		
Diarrhea	6%	9%
Nausea	3%	5%
Abdominal pain	3%	4%
Vomiting	1%	2%
Dyspeptic signs and symptoms	1%	2%
General		
Asthenic conditions	5%	7%
Cardiac		
Bradycardia	1%	3%
Skin and subcutaneous tissue		
Including rashes (generalized, macular, maculo-papular, erythematous), pruritus, eczema, dermatitis, dermatitis allergic	3%	5%

VII. Dosage and Administration

The only recommended dosage of MULTAQ is 400 mg twice daily in adults. MULTAQ should be taken as one tablet with the morning meal and one tablet with the evening meal.

Treatment with Class I or III antiarrhythmics (e.g., amiodarone, flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol) or drugs that are strong inhibitors of CYP3A (e.g., ketoconazole) must be stopped before starting MULTAQ.

References

1. Wolters Kluwer Health, Inc, ed. Drug Facts & Comparisons. St. Louis, MO. 2010.
2. Multaq [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; July 2009.

South Dakota Medicaid
P&T Committee Meeting
Xyrem® Review

I. Overview

Sodium oxybate (Xyrem), also referred to as gamma hydroxybutyrate (GHB), helps reduce the frequency of cataplexy attacks and improves daytime sleepiness. The FDA has placed tight restrictions on the use of this drug. Although the drug appears to be safe and effective for narcolepsy, it has a history of illegal and 'date-rape' use.

II. Pharmacology

The precise mechanism by which sodium oxybate produces an effect on cataplexy is unknown.

III. Pharmacokinetics

Sodium oxybate is absorbed rapidly following oral administration, with an absolute bioavailability of about 25%. The average time to peak plasma concentration ranged from 0.5 to 1.25 hours.

IV. Warnings/Precautions

Black Box Warning

Sodium oxybate is a gamma hydroxybutyrate (GHB), a known drug of abuse. Abuse has been associated with some important CNS adverse reactions, including death. Even at recommended doses, use has been associated with confusion, depression, and other neuropsychiatric reactions. Reports of respiratory depression occurred in clinical trials. Almost all of the patients who received sodium oxybate during clinical trials were receiving CNS stimulants.

Important CNS adverse reactions associated with abuse of sodium oxybate include respiratory depression, seizure, and profound decreases in level of consciousness, with instances of coma and death. For reactions that occurred outside of clinical trials, in people taking sodium oxybate for recreational purposes, the circumstances surrounding the reactions often are unclear (e.g., dose of sodium oxybate taken, the nature and amount of alcohol or any concomitant drugs).

Sodium oxybate is available through the Xyrem Success Program, using a centralized pharmacy. The Success Program provides educational materials to the prescriber and the patient explaining the risks and proper use of sodium oxybate and the required prescription form. Once it is documented that the patient has read and/or understands the materials, the drug will be shipped to the patient. The Xyrem Success Program also recommends patient follow-up every 3 months. Health care providers are expected to report all serious adverse reactions to the manufacturer.

Other Warnings/Precautions
Respiratory effects
CNS effects
Depression
Incontinence
Sleepwalking
Drug abuse and dependence
Hazardous tasks

V. Drug Interactions

Alcohol-the combined use of alcohol with sodium oxybate may result in potentiation of the CNS-depressant effects of sodium oxybate and alcohol.

CNS depressants/sedative hypnotics-do not use sodium oxybate in combination with sedative hypnotics or other CNS depressants.

VI. Adverse Events

A total of 717 narcoleptic patients were exposed to sodium oxybate in clinical trials. The most commonly observed adverse events associated with the use of sodium oxybate were: Headache (22%), nausea (21%), dizziness (17%), nasopharyngitis (8%), somnolence (8%), vomiting (8%), and urinary incontinence (7%).

VII. Dosage and Administration

Xyrem is required to be taken at bedtime while in bed and again 2.5 to 4 hours later. The recommended starting dose is 4.5g/night divided into two equal doses of 2.25g. The starting dose can then be increased to a maximum of 9g/night in increments of 1.5g/night One to two weeks are recommended between dosage increases to evaluate clinical response and minimize adverse effects. The effective dose range of Xyrem is 6 to 9g/night.

VIII. Utilization

Xyrem Utilization 07/01/09 to 06/30/10

Label Name	Rx Num	Total Reimb Amt	Cost per Script
XYREM 500 MG/ML ORAL SOLUTION	26	$36,973.65	$1,422.06
TOTALS 3 recipients	26	$36,973.65	

References

1. Wolters Kluwer Health, Inc, ed. Drug Facts & Comparisons. St. Louis, MO. 2010.
2. Xyrem [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; July 2005.