DUR Board Meeting
June 3, 2013
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
June 3, 2013
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and Approval of Minutes of 3/13 Meeting — Chair
    - Budget Update — Brendan
    - Second Review of Fulyzaq — Brendan
    - Second Review of Xeljanz — Brendan

3. New business
    - Review of Immediate Release Narcotic Utilization — HID
    - Review of Rayos — HID
    - Review of Diclegis — HID
    - Review of Sitavig — HID
    - Review of Onmel — HID
    - Review of Giazo — HID
    - Review of Delzicol — HID
    - Criteria Recommendations — HID
    - Upcoming Meeting Date/Agenda — Chair

4. Adjourn — Chair

Please remember to silence all cellular phones and pagers during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
March 11, 2013

Members Present: Norman Byers, John Savageau, Leann Ness, David Clinkenbeard, Carrie Sorenson, Cheryl Huber, Carlotta McCleary, Greg Pfister, Michael Booth, Jeffrey Hostetter

Members Absent: Steve Irsfeld, Todd Twogood, Russ Sobotta, Tanya Schmidt, James Carlson

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

HID Staff Present: Candace Rieth

Chair G. Pfister called the meeting to order at 1:00 pm. Chair G. Pfister asked for a motion to approve the minutes from the December meeting. N. Byers moved that the minutes be approved and C. Huber seconded the motion. Chair G. Pfister called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget Update
B. Joyce informed the board members that there is no new information since the last board meeting.

Genitourinary Smooth Muscle Relaxants (GSM) Second Review
A motion and second were made at the December meeting to place Genitourinary Smooth Muscle Relaxants on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Multiple Sclerosis Second Review
A motion and second were made at the December meeting to place agents used to treat multiple sclerosis (i.e., Aubagio) on prior authorization. The topic was brought up for a second review. Susan Grindle, representing Teva, spoke regarding Copaxone. Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Update on Medications Greater than $3,000
B. Joyce reviewed medications that cost greater than $3,000. Recently, three specialty medications came to market that prompted a closer review of high dollar agents. Utilization and new medication to market information was provided to the Board. B. Joyce informed the Board that the State is being vigilant to add these drugs to the PA list as soon as they come on the market. This not only ensures appropriate use, but also cost management when appropriate.

Fulyzaq Review
B. Joyce reviewed Fulyzaq clinical information with the board. There was no public comment. J. Hostetter made a motion to place Fulyzaq on prior authorization. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

Xeljanz Review
B. Joyce reviewed Xeljanz clinical information with the board. There was no public comment. T. Hartman, representing Pfizer, spoke regarding Xeljanz. J. Hostetter made a motion to place Xeljanz on prior authorization. G. Pfister seconded the motion. This topic will be brought up at the next meeting for finalization.

Asthma Management
Wendy Brown, Associate Professor at the NDSU College of Pharmacy and Clinical Coordinator of About the Patient, spoke regarding asthma management in the ND Medicaid population. About the Patient is currently writing a grant proposal to develop a Medication Therapy Management (MTM) program, for ND Medicaid recipients, designed to help build collaboration between prescribing health professionals, pharmacists, and patients with asthma in order to optimize medication use and disease control.

Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These proposed criteria will be added to the current set of criteria, and will be used in future DUR cycles. C. Huber moved to approve the new criteria and G. Pfister seconded the motion. Chair G. Pfister called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held June 3, 2013 in Bismarck. C. Sorenson made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

HEALTH INFORMATION DESIGNS

Fulyzaq
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Fulyzaq must meet the following criteria:
Note:

- **Patient must be 18 years of age or older.**
- **Patient must have non-infectious diarrhea.**
- **Patient must have HIV/AIDS and taking anti-retroviral therapy.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name:			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Qualifications for coverage:			
Requested Drug and Dosage: □ **Fulyzaq**	**Diagnosis for this request:** **Anti-retroviral therapy**		
Physician Signature		Date	

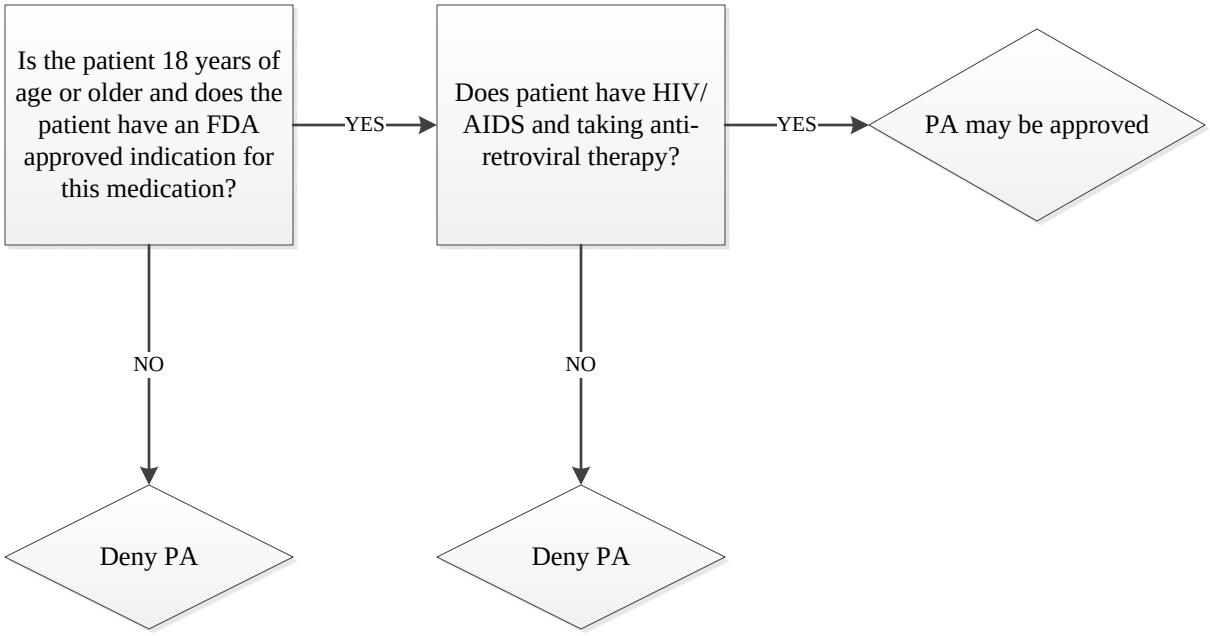
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Fulyzaq Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xeljanz
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Xeljanz must meet the following criteria:

Note:

- **Patient must have an inadequate response or intolerance to methotrexate.**
- **Patient must have a test for latent tuberculosis prior to starting Xeljanz.**
- **Patient must have current lab monitoring prior to starting Xeljanz (CBC, liver enzymes, lipid panel)**
- **Use with caution in patients that may be at increase risk of gastrointestinal perforations.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name:			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Xeljanz**	Diagnosis for this request:
TB test in the past 6 months □ Yes □ No Lab monitoring has occurred and measurements within acceptable limits (i.e., lymphocytes, neutrophils, hemoglobin, lipids, and liver enzymes) □ Yes □ NO Have or have had active hepatitis B or C virus □ Yes □ NO	Failed methotrexate therapy Start date: End date:
Physician Signature	Date

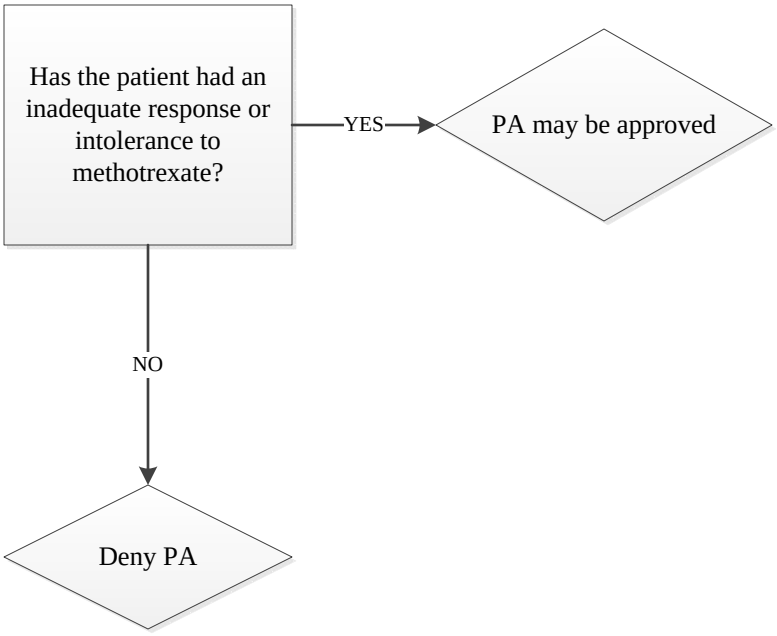
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Xeljanz Authorization Algorithm



North Dakota Immediate Release Narcotic Utilization		
02/26/12 - 02/25/13		
Label Name	**Rx Count**	**Reimb Amt**
HYDROMORPHONE 2 MG TABLET	625	$6,638.42
HYDROMORPHONE 4 MG TABLET	517	$11,691.12
HYDROMORPHONE 8 MG TABLET	74	$7,329.75
MEPERIDINE 50 MG TABLET	80	$1,634.03
METHADONE HCL 10 MG TABLET	356	$6,863.51
METHADONE HCL 5 MG TABLET	157	$1,382.07
MORPHINE SULFATE IR 15 MG TAB	198	$2,464.55
MORPHINE SULFATE IR 30 MG TAB	50	$1,269.29
OXYCODONE HCL 10 MG TABLET	553	$17,905.43
OXYCODONE HCL 15 MG TABLET	158	$5,327.05
OXYCODONE HCL 20 MG TABLET	57	$3,830.71
OXYCODONE HCL 30 MG TABLET	55	$2,956.72
OXYCODONE HCL 5 MG CAPSULE	5	$98.54
OXYCODONE HCL 5 MG TABLET	1717	$31,544.78
OXYMORPHONE HCL 5 MG TABLET	8	$2,497.08
Total Recipients 1062	**4610**	**$103,433.05**

Top 10 Counties by Script Count	
County	**Percentage**
Cass	19.96%
Burleigh	12.80%
Grand Forks	8.42%
Rolette	8.24%
Stutsman	6.82%
Morton	6.70%
Ward	5.17%
Stark	3.69%
Barnes	3.17%
Walsh	2.83%

Top 20 Prescribers by Script Count	
Specialty	**Script Count**
NP	131
Family Practice	124
PA	118
Physiatrist	116
Physical Med and Rehab	90
Family Practice	84
Physical Med and Rehab	71
Family Practice	68
Family Practice	59
Physical Med and Rehab	54
Orthopedics	53
Family Practice	50
Orthopedics	50
NP	48
Family Practice	47
Family Practice	44
Family Practice	44
NP	43
Internal Medicine	42
Family Practice	41

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
HYDROMORPHONE 8 MG TABLET	360	4	90.00
OXYCODONE HCL 10 MG TABLET	150	3	50.00
OXYCODONE HCL 5 MG TABLET	480	10	48.00
OXYCODONE HCL 5 MG TABLET	200	6	33.33
OXYCODONE HCL 5 MG TABLET	250	8	31.25
METHADONE HCL 10 MG TABLET	900	30	30.00
OXYCODONE HCL 5 MG TABLET	120	4	30.00
OXYCODONE HCL 5 MG TABLET	140	5	28.00
OXYCODONE HCL 5 MG TABLET	250	9	27.78
HYDROMORPHONE 8 MG TABLET	360	14	25.71
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
OXYCODONE HCL 5 MG TABLET	200	8	25.00
HYDROMORPHONE 4 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
OXYCODONE HCL 5 MG TABLET	24	1	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
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OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	360	15	24.00

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
OXYCODONE HCL 5 MG TABLET	360	15	24.00
OXYCODONE HCL 5 MG TABLET	70	3	23.33
HYDROMORPHONE 2 MG TABLET	300	13	23.08
OXYCODONE HCL 5 MG TABLET	45	2	22.50
OXYCODONE HCL 5 MG TABLET	90	4	22.50
OXYCODONE HCL 5 MG TABLET	224	10	22.40
OXYCODONE HCL 5 MG TABLET	224	10	22.40
OXYCODONE HCL 5 MG TABLET	336	15	22.40
HYDROMORPHONE 2 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
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HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
OXYCODONE HCL 5 MG TABLET	200	9	22.22
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	200	10	20.00
METHADONE HCL 5 MG TABLET	280	14	20.00
MORPHINE SULFATE IR 15 MG TAB	100	5	20.00
OXYCODONE HCL 10 MG TABLET	40	2	20.00
OXYCODONE HCL 10 MG TABLET	60	3	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	600	30	20.00

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
OXYCODONE HCL 5 MG TABLET	40	2	20.00
OXYCODONE HCL 5 MG TABLET	60	3	20.00
OXYCODONE HCL 5 MG TABLET	100	5	20.00
OXYCODONE HCL 5 MG TABLET	100	5	20.00

Top 20 Diagnoses for Patients Receiving 10 or more IR scripts 02/26/12 – 02/25/13		
DX Code	**DX Description**	**Count**
25000	DIABETES UNCOMPL TYPE II	2,161
4019	UNSPECIFIED ESSENTIAL HYPERTENSION	1,718
33829	OTHER CHRONIC PAIN	1,468
5856	END STAGE RENAL DISEASE	1,400
78900	ABDOMINAL PAIN UNS SITE	1,381
3051	TOBACCO USE DISORDER	1,182
28521	ANEMIA CHRONIC KIDNEY DISEASE	1,169
V560	ENCOUNTER FOR EXTRACORP DIALYSIS	1,155
7242	LUMBAGO	1,093
40391	UNS KID HYPER W CKD STAGE V-ESRD	1,043
78650	UNSPEC CHEST PAIN	1,025
58881	SEC HYPERPARATHYROIDISM RENAL	987
496	CHRONIC AIRWAY OBSTRUCTION OTHER	986
78701	NAUSEA WITH VOMITING	960
7840	HEADACHE	959
311	DEPRESSIVE DISORDER OTHER	923
V5869	ENCOUNTER LONG TERM USE OTH DRUGS	839
3384	CHRONIC PAIN SYNDROME	803
30000	ANXIETY STATE UNSPECIFIED	784
25040	DIABETES RENAL MANIF TYPE II	769

North Dakota Medicaid
Pharmacotherapy Review
Rayos®

I. Indication

Rayos is a new extended release dosage form for prednisone indicated:

- As an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation.
- For the treatment of certain endocrine conditions.
- For palliation of certain neoplastic conditions.

II. Warnings and Precautions

- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia: Monitor patients for these conditions with chronic use. Taper doses gradually for withdrawal after chronic use.
- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination, or reactivation of latent infection. Signs and symptoms of infection may be masked.
- Elevated blood pressure, salt and water retention, and hypokalemia: Monitor blood pressure and sodium, potassium serum levels.
- GI perforation: Increased risk in patients with certain GI disorders. Signs and symptoms may be masked.
- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis. Existing conditions may be aggravated.
- Decreases in bone density: Monitor bone density in patients receiving long term corticosteroid therapy.
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure if corticosteroid therapy is continued for more than 6 weeks.
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids.
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy.
- Use in pregnancy: Fetal harm can occur with first trimester use. Apprise women of potential harm to fetus.

III. Drug Interactions

- Anticoagulant agents: May enhance or diminish anticoagulant effects.
- Antidiabetic agents: May increase blood glucose concentrations. Dose adjustments of antidiabetic agents may be required.

- CYP3A4 inducers and inhibitors: May, respectively, increase or decrease clearance of corticosteroids, necessitating dose adjustment.
- Cyclosporine: Increase in activity of both cyclosporine and corticosteroid when administered concurrently. Convulsions have been reported with concurrent use.
- NSAIDs including aspirin and salicylates: Increased risk of gastrointestinal side effects.

IV. Adverse Reactions

Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.

V. Dosage and Administration

Individualize dosing based on disease severity and patient response. The timing of administration should take into account the delayed-release pharmacokinetics and the disease or condition being treated:

- Initial dose: RAYOS 5 mg administered once per day. Patients currently on immediate-release prednisone, prednisolone, or methylprednisolone should be switched to RAYOS at an equivalent dose based on relative potency.
- Maintenance dose: Use lowest dosage that will maintain an adequate clinical response.
- Discontinuation: Withdraw gradually if discontinuing long-term or high-dose therapy.
- RAYOS should be taken daily with food.
- RAYOS should be swallowed whole and not broken, divided, or chewed.

VI. Cost

Rayos costs approximately $7.50 per 5mg tablet.

Reference

1. Rayos® [prescribing information]. Deerfield, IL. Horizon Pharma USA, Inc.; January 2013.

North Dakota Medicaid
Pharmacotherapy Review
Diclegis®

I. Indication

Diclegis is a fixed dose combination drug of doxylamine succinate (antihistamine) and pyridoxine hydrochloride (vitamin B6 analog) indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

II. Warnings and Precautions

- Avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery.
- Concurrent use with alcohol or other CNS depressants is not recommended.
- Use with caution in patients with asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and urinary bladder-neck obstruction.

III. Contraindications

- Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation.
- Monoamine oxidase (MAO) inhibitors.

IV. Drug Interactions

- Severe drowsiness can occur when used in combination with alcohol or other sedating medications.

V. Adverse Reactions

The most common adverse reaction with Diclegis (≥5% and exceeding the rate in placebo) is somnolence.

VI. Dosage and Administration

Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon and two at bedtime).

VII. Cost

Diclegis costs approximately $5 per tablet.

Reference

1. Diclegis® [prescribing information]. Bryn Mawr, PA. Duchesnay USA, Inc.; April 2013.

North Dakota Medicaid
Pharmacotherapy Review
Sitavig®

I. Indication

Sitavig (acyclovir) is an antiviral medication indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

II. Contraindications

- Known hypersensitivity to acyclovir, milk protein concentrate, or any other component of the product.

III. Drug Interactions

- Due to the low dose and minimal systemic absorption of Sitavig, drug interactions are unlikely.

IV. Adverse Reactions

The most common adverse reactions (≥1%) are headache and application site pain.

V. Dosage and Administration

- Application of one Sitavig 50mg buccal tablet as a single dose to the upper gum (canine fossa) region.
- Sitavig should be applied within one hour after the onset of prodromal symptoms and before the appearance of any signs of herpes labialis.
- Do not crush, chew, suck, or swallow tablets.

Reference

1. Sitavig® [prescribing information]. Bioalliance Pharma SA.; April 2013.

North Dakota Medicaid
Pharmacotherapy Review
Onmel®

I. Indication

Onmel (itraconazole) is an azole antifungal indicated for the treatment of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes*.

II. Warnings and Precautions

Black Box Warning

WARNING: CONGESTIVE HEART FAILURE, CARDIAC EFFECTS AND DRUG INTERACTIONS

See full prescribing information for complete boxed warning.

- **Do not administer for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.**
- If signs or symptoms of congestive heart failure occur during administration, discontinue administration.
- Negative inotropic effects were seen when itraconazole was administered intravenously to dogs and healthy human volunteers.

- **Drug Interactions: Co-administration of certain drugs is contraindicated. See complete boxed warning.**
- May increase plasma concentrations of drugs metabolized by thecytochrome P450 3A4 isoenzyme system (CYP3A4) pathway.
- Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death have occurred in patients using certain drugs. See complete boxed warning.

- Cases of congestive heart failure (CHF), peripheral edema, and pulmonary edema have been reported with itraconazole administration among patients being treated for onychomycosis and/or systemic fungal infections.
- Cardiac dysrhythmias
- Cardiac disease
- Hepatic effects
- Calcium channel blockers
- Neuropathy
- Hearing loss

III. Contraindications

- Do not administer for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as CHF or a history of CHF.
- Do not administer for the treatment of onychomycosis to pregnant patients or to women contemplating pregnancy.
- Co-administration of cisapride, dofetilide, ergot alkaloids such as dihydroergotamine, ergotamine, ergometrine (ergonovine), and methylergometrine (methylergonovine); felodipine, levacetylmethadol (levomethadyl), lovastatin, methadone, oral

midazolam, nisoldipine, pimozide, quinidine, simvastatin, and triazolam with Onmel is contraindicated.
- Anaphylaxis and hypersensitivity have been reported with use of itraconazole.

IV. Drug Interactions

- Concomitant administration of ONMEL Tablets with certain drugs metabolized by the cytochrome P450 3A4 isoenzyme system (CYP3A4) or transported by P-glycoprotein may result in increased plasma concentrations of those drugs, leading to potentially serious and/or life-threatening adverse events.
- Drug Interactions with the following drugs or classes of drugs may occur: Antiarrhythmics, Anticonvulsants, Anti-HIV Agents, Antimycobacterials, Antineoplastics, Antipsychotics, Benzodiazepines, Calcium Channel Blockers, Gastric Acid Suppressors/Neutralizers, Gastrointestinal Motility Agents, HMG CoA-Reductase Inhibitors, Macrolide Antibiotics, Oral Hypoglycemic Agents, Polyenes, Opiate Analgesics. Not all drug interactions are included in Highlights. See Full Prescribing Information for complete listing.

V. Adverse Reactions

- Most common adverse reactions observed in the treatment phase of the onychomycosis clinical trial (>1%) are upper respiratory tract infections, increased hepatic enzymes, hypoacusis, headache, abdominal pain, diarrhea, nausea, fatigue, arrhythmia, cough, sore throat and back pain.
- Itraconazole has been associated with rare cases of serious hepatotoxicity, including liver failure and death.

VI. Dosage and Administration

Onychomycosis of the toenail: recommended dose is 200mg once daily for 12 consecutive weeks.

VII. Cost

The cost of Onmel is approximately $30 per tablet.

Reference

1. Onmel® [prescribing information]. Greensboro, NC. Merz Pharmaceuticals, LLC; November 2012.

North Dakota Medicaid
Pharmacotherapy Review
Giazo®

I. Indication

Giazo is locally acting aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

II. Warnings and Precautions

- Exacerbation of the symptoms of ulcerative colitis was reported. Observe patients closely for worsening of these symptoms while on treatment.
- Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment.
- Use with caution with pre-existing liver disease.

III. Contraindications

Giazo is contraindicated in patients with hypersensitivity to salicylates or to any of the components of Giazo tablets or balsalazide metabolites.

IV. Adverse Reactions

Most common adverse reactions (incidence ≥2%) in male ulcerative colitis patients are anemia, diarrhea, pharyngolaryngeal pain, and urinary tract infection.

V. Dosage and Administration

Three 1.1g Giazo tablets 2 times a day (6.6 g/day) with or without food for up to 8 weeks.

VI. Cost

Giazo costs approximately $5 per tablet.

Reference

1. Giazo® [prescribing information]. Raleigh, NC. Salix Pharmaceuticals, Inc.; June 2012.

North Dakota Medicaid
Pharmacotherapy Review
Delzicol®

I. Indication

Delzicol is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

II. Warnings and Precautions

- Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment.
- Mesalamine-induced acute intolerance syndrome has been reported. Observe patients closely for worsening of these symptoms while on treatment.
- Use caution when treating patients who are hypersensitive to sulfasalazine.
- Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported.
- Hepatic failure has been reported in patients with pre-existing liver disease. Use caution when treating patients with liver disease.
- Upper gastrointestinal (GI) tract obstruction may delay onset of action.

III. Contraindications

Delzicol is contraindicated in patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of Delzicol.

IV. Adverse Reactions

The most common adverse reactions (observed in ≥5% of patients) were abdominal pain, eructation, pain, headache, back pain, diarrhea, rash, dyspepsia, rhinitis, flu syndrome, asthenia, flatulence, vomiting, fever, arthralgia, constipation, and gastrointestinal bleeding.

V. Drug Interactions

- Nephrotoxic agents including NSAIDs (renal reactions)
- Azathioprine or 6-mercaptopurine (blood disorders)

VI. Dosage and Administration

- For the treatment of mildly to moderately active ulcerative colitis, 800mg three times daily.
- For the maintenance of remission of ulcerative colitis, 1.6g daily, in divided doses.
- Swallow whole without cutting, breaking, or chewing.
- Dose at least 1 h before or 2 h after a meal.
- Two Delzicol 400mg capsules have not been shown to be bioequivalent to one Asacol HD delayed-release 800mg tablet.

VII. Cost

Delzicol costs approximately $3 per tablet.

Reference

1. Delzicol® [prescribing information]. Rockaway, NJ. Warner Chilcott (US), LLC; February 2013.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2nd QUARTER 2013

Criteria Recommendations ***Approved*** ***Rejected***

1. Zolpidem IR / Therapeutic Appropriateness _____ _____

Alert Message: The zolpidem-containing product may be over-utilized. The recommended dosing range for immediate-release zolpidem in non-elderly adults is 5 to10 mg daily, immediately before bedtime. A dose greater than 5 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 5 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem IR

Gender: Female
Max Dose: 5mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

2. Zolpidem IR / Therapeutic Appropriateness _____ _____

Alert Message: The zolpidem-containing product may be over-utilized. The recommended dosing range for immediate-release zolpidem in non-elderly adults is 5 to10 mg daily, immediately before bedtime. A dose greater than 5 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 5 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem IR

Gender: Male
Max Dose: 10mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

3. Zolpidem CR / Overutilization _____ _____

Alert Message: Extended-release zolpidem may be over-utilized. The recommended dosing range for zolpidem ER in non-elderly adults is 6.25 to 12.5 mg daily, immediately before bedtime. A dose greater than 6.25 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 6.25 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem CR

Gender: Female
Max Dose: 6.25mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

4. Zolpidem CR / Overutilization _____ _____

Alert Message: Extended-release zolpidem may be over-utilized. The recommended dosing range for zolpidem ER in non-elderly adults is 6.25 to12.5 mg daily, immediately before bedtime. A dose greater than 6.25 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 6.25 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem CR

Gender: Male
Max Dose: 12.5mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

5. Intermezzo / Overutilization Females 18-64 yoa _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for women is 1.75 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for men is 3.5mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Gender: Female
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

6. Intermezzo / Overutilization Males 18-64 yoa _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for men is 3.5 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for females is 1.75 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 3.5 mg/day
Gender: Male
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

7. Intermezzo / Overutilization 65 yoa and older _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for geriatric patients is 1.75 mg. A pharmacokinetic study of 1.75 and 3.5 mg doses of sublingual zolpidem showed that the plasma Cmax and AUC in elderly subjects following the 3.5 mg dose was higher by 34% and 30%, respectively, than the non-elderly subjects.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Age Range: ≥65 yoa

References:
Intermezzo Prescribing Iq3207nformation, 2012, Purdue Pharma.

8. Intermezzo / Overutilization Hepatic Impairment _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for patients with hepatic impairment is 1.75 mg. In a pharmacokinetic study patients with chronic hepatic insufficiency or cirrhosis taking oral zolpidem exhibited increased pharmacokinetic parameters as compared to subjects with normal hepatic function.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

9. Intermezzo / CNS Depressants _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) when taken concurrently with a CNS depressant is 1.75 mg. Concomitant use of these agents may result in additive CNS depression.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Intermezzo		Narcotics
		Benzodiazepines
		Barbiturates
		Sedative/Hypnotics
		Muscle Relaxants
		Antipsychotics
		Antihistamines

Max Dose: 1.75mg/day

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

10. Pioglitazone / Gemfibrozil _____ _____

Alert Message: The maximum recommended dose of a pioglitazone-containing product is 15 mg once daily when used in combination with strong CYP2C8 inhibitors (e.g., gemfibrozil).

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Pioglitazone		Gemfibrozil
Pioglitazone/Metformin IR		
Pioglitazone/Alogliptin		

Max Dose: 15 mg/day of pioglitazone

References:
Facts & Comparison, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Actos Prescribing Information, August 2012, Takeda Pharmaceuticals.
ActoPlus Met Prescribing Information, September 2012, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

11. Actoplus Met XR & Duetact / Gemfibrozil _____ _____

Alert Message: The concurrent use of a pioglitazone-containing agent with a CYP2C8 inhibitor (e.g., gemfibrozil) can cause a significant increase in pioglitazone plasma concentrations. If an inhibitor of CYP2C8 is started or stopped during pioglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Pioglitazone/Metformin XR	Gemfibrozil	
Pioglitazone/Glimepiride		

References:
ActoPlus Met XR Prescribing Information, October 2012, Takeda Pharmaceuticals.
Duetact Prescribing Information, October 2012, Takeda Pharmaceuticals.

12. Pioglitazone - All / Rifampin _____ _____

Alert Message: The concurrent use of a pioglitazone-containing agent with a CYP2C8 inducer (e.g., rifampin) can cause a significant decrease in pioglitazone plasma concentrations. If an inducer of CYP2C8 is started or stopped during pioglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response, without exceeding the maximum recommended daily dose of 45 mg for pioglitazone.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Pioglitazone-All	Rifampin	

References:
Actos Prescribing Information, August 2012, Takeda Pharmaceuticals.
ActoPlus Met Prescribing Information, September 2012, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
ActoPlus Met XR Prescribing Information, October 2012, Takeda Pharmaceuticals.
Duetact Prescribing Information, October 2012, Takeda Pharmaceuticals.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

13. Rosiglitazone - All / Rifampin _____ _____

Alert Message: The concurrent use of a rosiglitazone-containing agent with a CYP2C8 inducer (e.g., rifampin) can cause a significant decrease in rosiglitazone plasma concentrations. If an inducer of CYP2C8 is started or stopped during rosiglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rosiglitazone-All	Rifampin	

References:
Avandia Prescribing Information, May 2011, GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

14. Rosiglitazone - All / Gemfibrozil _____ _____

Alert Message: The concurrent use of a rosiglitazone-containing agent with a CYP2C8 inhibitor (e.g., gemfibrozil) can cause a significant increase in rosiglitazone plasma concentrations. If an inhibitor of CYP2C8 is started or stopped during rosiglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rosiglitazone- All	Gemfibrozil	

References:
Avandia Prescribing Information, May 2011, GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

15. Alogliptin / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Nesina (alogliptin) in patients with normal renal function or mild renal impairment is 25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin		CKD Stage 3-5
		ESRD
		Hypertensive CKD

Max Dose: 25mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

16. Alogliptin / Moderate Renal Impairment Dosing _____ _____

Alert Message: The maximum recommended dose of Nesina (alogliptin) in patients with moderate renal impairment (CrCl 30 to < 60 mL/min) is 12.5 mg once daily. Patients with severe renal impairment or ESRD should not receive more than 6.25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin		CKD Stage 3
		CKD unspecified
		Hypertensive CKD

Max Dose: 12.5mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

17. Alogliptin / Severe Renal Impairment or ESRD Dosing _____ _____

Alert Message: The maximum recommended dose of Nesina (alogliptin) in patients with severe renal impairment or ESRD (CrCl< 30 mL/min) is 6.25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin		CKD Stage 4-5
		ESRD
		Hypertensive CKD

Max Dose: 6.25mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

18. Alogliptin-All / Pancreatitis _____ _____

Alert Message: There have been postmarketing reports of acute pancreatitis in patients taking Nesina (alogliptin). After initiation of any alogliptin-containing product, patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected the alogliptin-containing agent should be promptly discontinued and appropriate management should be initiated.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Alogliptin	Pancreatitis	
Alogliptin/Metformin		
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

19. Alogliptin-All / Hepatic Effects _____ _____

Alert Message: There have been postmarketing reports of fatal and non-fatal hepatic failure in patients taking Nesina (alogliptin). If liver injury is detected, promptly interrupt alogliptin-containing therapy and assess patient for probable cause. Do not restart the alogliptin-containing product if liver injury is confirmed and no alterative etiology can be found.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Alogliptin		
Alogliptin/Metformin		
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

20. Alogliptin-All / Insulin & Sulfonylureas _____ _____

Alert Message: The concurrent use of an alogliptin-containing product (Nesina, Kazano and Oseni) with insulin or an insulin secretagogue (e.g., sulfonylurea) may result in hypoglycemia. A lower dose of the sulfonylurea or insulin may be required to minimize the risk of hypoglycemia.

Conflict Code: DD – Drug/Drug Interactions
Drugs/Diseases

Util A	Util B	Util C
Alogliptin	Insulin	
Alogliptin/Metformin	Sulfonylureas	
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

21. Alogliptin-Pioglitazone / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended daily dose of Oseni (alogliptin/pioglitazone) in patients with normal renal function or mild renal impairment is 25 mg alogliptin and 45mg pioglitazone.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin/Pioglitazone		CKD Stage 3-5
		ESRD
		Hypertensive CKD

Max Dose: 25mg/day alogliptin

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

22. Alogliptin-Pioglitazone / Moderate Renal Impairment Dosing _____ _____

Alert Message: The manufacturer's maximum recommended dose of Oseni (alogliptin/pioglitazone) in patients with moderate renal impairment (CrCl 30 to < 60 mL/min) is 12.5 mg of alogliptin once daily. Alogliptin/pioglitazone use is not recommended for patients with severe renal impairment or ESRD requiring dialysis.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin/Pioglitazone		CKD Stage 3
		CKD unspecified
		Hypertensive CKD

Max Dose: 12.5mg/day

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

23. Alogliptin-Metformin / Overutilization _____ _____
Alert Message: The manufacturer's maximum recommended daily dose of Kazano (alogliptin/metformin) is 25 mg alogliptin and 2000mg metformin.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin/Metformin		Renal Impairment

Max Dose: 25mg/day alogliptin

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

24. Alogliptin-Metformin / Metabolic Acidosis _____ _____
Alert Message: Kazano (alogliptin/metformin) use is contraindicated in patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Alogliptin/Metformin	Acidosis	

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

25. Alogliptin-All / Duplicate Therapy _____ _____
Alert Message: Therapeutic duplication of alogliptin-containing products may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Alogliptin		
Alogliptin/Pioglitazone		
Alogliptin/Metformin		

References:
Nesina Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

26. Alogliptin / Nonadherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Nesina (alogliptin). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Alogliptin		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

27. Alogliptin-Pioglitazone / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Oseni (alogliptin/pioglitazone). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Alogliptin/Pioglitazone		

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

28. Alogliptin-Metformin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Kazano (alogliptin/metformin). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Alogliptin/Metformin		

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

29. Alogliptin-All / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of alogliptin-containing products (Nesina, Kazano and Oseni) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Alogliptin Alogliptin/Metformin Alogliptin/Pioglitazone		

Age Range: 0-18 yoa

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

30. Metformin – All / Hepatic Impairment _____ _____

Alert Message: The use of metformin-containing products should be avoided in patients with clinical or laboratory evidence of hepatic disease. Metformin can, rarely, cause lactic acidosis and impaired hepatic function can significantly limit clearance of lactate. Metformin use in this patient population may increase the risk of lactic acidosis..

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Metformin-All	Hepatic Impairment	

References:

Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 3013 Elsevier/Gold Standard.