DUR Board Meeting
August 20th, 2007
Heritage Center
Rooms A and B
1pm

HEALTH INFORMATION DESIGNS

June 13th, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held August 20th, 2007 at 1:00pm

Heritage Center
Rooms A and B
612 East Blvd
Bismarck, ND

Please remember to silence all pagers and cell phones prior to the start of the meeting.

North Dakota Medicaid
DUR Board Meeting
Agenda
Heritage Center
Rooms A and B
August 20th, 2007
1pm

1. Administrative items
   - Travel vouchers
   - Board Members Sign In

2. Old Business

• Review and approval of minutes of 06/04/07 meeting	Chairman
• Budget update	Brendan
• Amrix Review	HID
• Synagis Review	HID
• Tekturna Review	HID
• Xopenex Review	HID
• Ketek Review	HID
• Review of Oral Antineoplastic Agents	HID
• Review of Antiretroviral Agents	HID
• Review of High Cost Medications	HID
• Yearly PA Review of Growth Hormone/IGF-1 Agents	HID

3. New Business

• Review of ADHD Agents	HID
• Criteria Recommendations	Brendan
• Upcoming meeting date/agenda	Chairman

4. Adjourn — Chairman

Please remember to turn all cellular phones and pagers to silent mode during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 4th, 2007

Members Present: Albert Samuelson, Patricia Churchill, Cheryl Huber, Norman Byers, Carrie Sorenson, Todd Twogood, Greg Pfister, Scott Setzepfandt, Leann Ness and Carlotta McCleary.
Medicaid Pharmacy Department: Brendan Joyce, Gary Betting
HID Staff Present: Candace Rieth
Members Absent: Bob Treitline and John Savageau.

Chairman, C. Huber, called the meeting to order at 1:00pm. She asked for a motion to approve the minutes from the March 12th, 2007 meeting. N. Byers moved that the minutes be approved and T. Twogood seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Synagis Review:
B. Joyce updated the Board regarding Synagis utilization. The Department would like to develop a patient registry for Synagis. Potential Synagis patients would be submitted to the Department by physicians. A registry would allow the Department to track Synagis patients and utilization. It would also allow the Department to track patients that should receive Synagis and do not. Currently, there is not a good system in place to track Synagis prescriptions due to billing issues. T. Twogood suggested that the Department disseminate Synagis information to primary care physicians as well as neonatologists. Dr. Rafael Ocejo spoke regarding the form type that should be used for Synagis. Dr. Ocejo also asked if the Department could work with the Health Department to determine when the Synagis season should begin. Dr. Ocejo said that doing this would prevent utilization of Synagis before the true season starts. Dr. Karen Brown spoke regarding health officials determining the beginning of the Synagis season. Dr. Brown is concerned that this would require all patients be cultured for RSV at a greater expense to the State. A motion was made by A. Samuelson to require a registry for Synagis. P. Churchill seconded the motion. This topic will be brought before the Board in August for finalization.

Budget Update:
B. Joyce had no new information to present regarding the budget.

Review of Methadone
At the March meeting A Samuelson asked for Methadone information including trends over time, the distribution of patients using methadone and patients using methadone with multiple prescribers. C. Rieth reviewed this data with the Board. T. Twogood suggested that the Department review profiles of the patients receiving Methadone from 3 or more prescribers.

Review of Qualaquin
B. Joyce informed the Board that all quinine products will eventually leave the market with Qualaquin being the only remaining product. Qualaquin is approved for malaria. At the March DUR meeting, a motion and second was made to place Qualaquin on prior authorization. A voice vote was taken with no audible dissent. Motion passed to place Qualaquin on prior authorization.

Yearly Review of Prior Authorization
Once a year, the Board reviews products that were placed on prior authorization. This allows the Board a chance to review the prior authorization forms and criteria. ACE-Inhibitors were reviewed. No action will be taken regarding the ACE-Inhibitor form or criteria. Sedative/Hypnotics were reviewed. No action will be taken regarding the Sedative/Hypnotic form or criteria.

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next two years, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

Review of Amrix
Amrix is a new extended release skeletal muscle relaxant containing cyclobenzaprine. B. Joyce stated that all cyclobenzaprine is for short term use, and the current immediate release product appears to be therapeutically effective. There was no public comment. A motion was made by N. Byers to require a prior authorization on Amrix. G. Pfister seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Janumet
Janumet is a combination medication containing sitagliptin (Januvia) with metformin for treating type 2 diabetes. The pricing of two pills of Janumet is equivalent to one pill of Januvia; therefore this topic was tabled.

Review of Tekturna
Tekturna is a new antihypertensive medication that is the first direct rennin inhibitor approved by the FDA. Criteria for approval would be similar to the ARBs as there is no outcome data to suggest Tekturna should be used first line before ACE inhibitors or ARBs. There was public comment by Dana Meier, representing Novartis. She reviewed Tekturna related prescribing information with the Board. Randy Troxill, representing Novartis, spoke regarding pricing of Tekturna in relation to ACE-Is and ARBs. A motion was made by N. Byers to require a prior authorization on Tekturna. P. Churchill seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Xopenex
The final discontinuation date for CFC inhalers is December 31, 2008. With the absence of these inhalers, HFA inhalers will be the only option for albuterol/levalb uterol in the near future. With the switch from CFC inhalers to HFA inhalers, the Department anticipates an increase in total claims cost of at least 170,000 dollars a year. The Department would like to group the albuterol HFA and levalbuterol HFA products together and choose the preferred product based on the cheapest HFA, post-rebate. Unfortunately, the Department is unable to disclose rebate dollars to the Board to show the major difference between the HFA albuterol/levalbuterol products. There was public comment by Jason Anderson, representing Sepracor. Brian Easton, representing Sepracor, spoke regarding the Xopenex standing orders given to physicians in the past. A motion was made by T. Twogood to table the issue of prior authorization for the HFA products. A. Samuelson seconded the motion. This motion did not pass (failed by two votes after post-meeting review). C. Sorenson asked if modification of the PA form is acceptable. B. Joyce said that the form and criteria could be changed and an age restriction could also be added. T. Twogood suggested that patients under the age of 16 be exempt. C. Sorenson made a motion to modify the PA form to exclude patients 16 and below. G. Pfister seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Ketek
In light of recent FDA warnings, the Department would like to monitor utilization of Ketek. The Board discussed placing Ketek on prior authorization. A motion was made by C. Sorenson to place Ketek on prior authorization with an additional criterion of allergy to quinolones and tetracyclines. T. Twogood seconded the motion. This topic will be brought before the Board in August for finalization.

High Cost Medications
House Bill 1459 directs the Department to review expensive medical procedures for prior authorizations. The Department would also like to extend this review to medications. This would allow reconciliation of data to determine incorrect billings. The Department would like for the Board to review utilization data and make suggestions on how best to monitor these products. This topic will come up for further discussion at a later meeting.

Criteria Recommendations
The enclosed recommended RDUR criteria are developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These criteria will be added to the current set of criteria, and will be used in future DUR cycles. P. Churchill moved to approve the new criteria and C. Sorrenson seconded the motion. The motion was approved by voice vote with no audible dissent.

HIV/AIDS Review
The HIV/AIDS Review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. The Legislative Council gave a deadline of October, 2008 for these reviews to be completed. A periodic report will also be sent to the Council as each class is reviewed. T. Twogood suggested getting a consult from one of the Infectious Disease doctors that are currently prescribing to North Dakota Medicaid patients. C. Huber and B. Joyce will contact these physicians for guidance regarding this class of medications.

Oral Antineoplastic Review
B. Joyce reviewed utilization data of the antineoplastic medications. The Department suggests a registration process for the antineoplastic class of medications. Having a registration would allow physicians to include study information the patients are enrolled in as well as peer reviewed literature endorsing utilization of specific products. Most private insurance companies require a prior authorization process with this class of medications. A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce will contact these physicians for guidance regarding this class of medications.

The next DUR board meeting will be August 20th, 2007. B. Joyce reviewed future agenda items. These include ADHD, HIV/AIDS and Cancer. P. Churchill made a motion to adjourn the meeting and N. Byers seconded. Chair C. Huber adjourned the meeting at 3:50 pm.

AMRIX PRIOR AUTHORIZATION
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

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

ND Medicaid requires that patients try and fail generic cyclobenzaprine.
****Note:***

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

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG:	**Requested Dosage:** (must be completed)

Qualifications for coverage:

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

□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Physician Signature: Date:

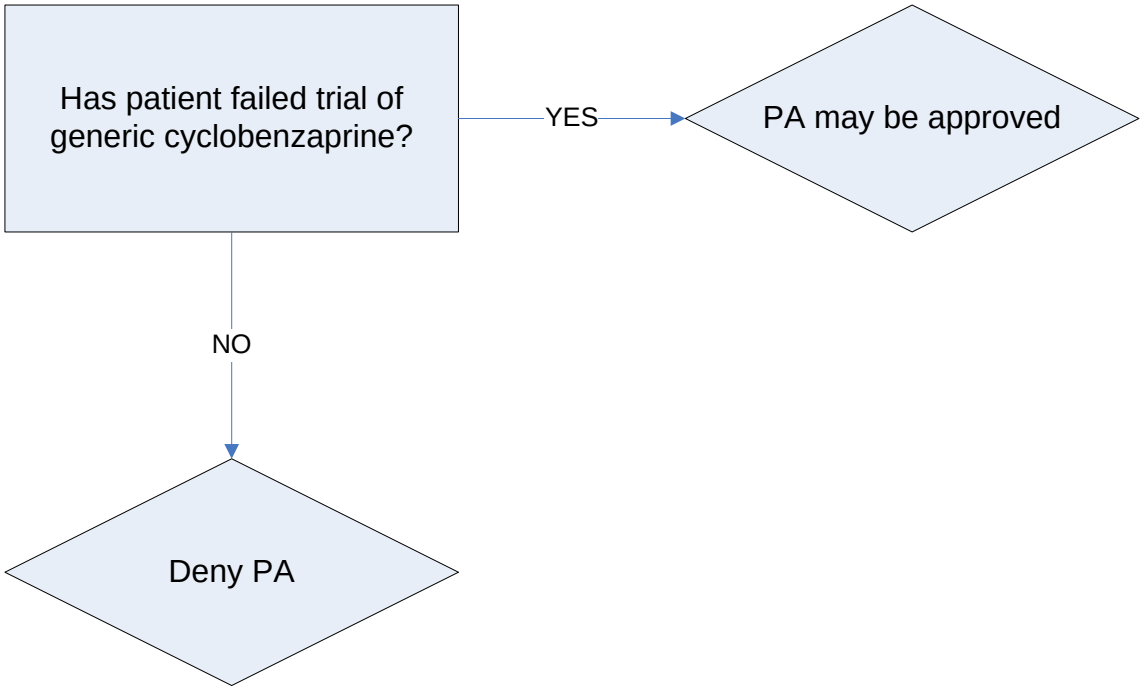
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Amrix Authorization Algorithm



AAP 2006 REDBOOK RECOMMENDATIONS FOR THE PREVENTION OF RSV

CLINICAL MANIFESTATIONS: Respiratory syncytial virus (RSV) causes acute respiratory tract illness in patients of all ages. In infants and young children, RSV is the most important cause of bronchiolitis and pneumonia. During the first few weeks of life, particularly among preterm infants, infection with RSV may produce minimal respiratory tract signs. Lethargy, irritability, and poor feeding, sometimes accompanied by apneic episodes, may be the presenting manifestations in infants. Most previously healthy infants infected with RSV do not require hospitalization, and many who are hospitalized improve with supportive care and are discharged in fewer than 5 days. Characteristics that increase the risk of severe or fatal RSV infection are preterm birth; cyanotic or complicated congenital heart disease, especially conditions causing pulmonary hypertension; underlying pulmonary disease, especially chronic lung disease of prematurity; and immunodeficiency disease or therapy causing immunosuppression at any age. The association between RSV bronchiolitis early in life and subsequent reactive airway disease remains poorly understood. After RSV bronchiolitis, many children will have episodes of recurrent wheezing, which usually diminish in subsequent years. Some children may develop wheezing at older ages or develop long-term abnormalities in pulmonary function. This association may reflect an underlying predisposition to reactive airway disease rather than a direct consequence of RSV infection.

Almost all children are infected at least once by 2 years of age, and reinfection throughout life is common. Respiratory syncytial virus infection in older children and adults usually manifests as upper respiratory tract illness, but more serious disease involving the lower respiratory tract also can develop in immunocompromised patients or in the elderly. Exacerbation of acute asthmatic bronchitis or other chronic lung conditions may occur.

ETIOLOGY: Respiratory syncytial virus is an enveloped RNA paramyxovirus that lacks neuraminidase and hemagglutinin surface glycoproteins. Two major strains (groups A and B) have been identified and often circulate concurrently. The clinical and epidemiologic significance of strain variation has not been determined, but some evidence suggests that antigenic differences may affect susceptibility to infection and that some strains may be more virulent than other strains.

EPIDEMIOLOGY: Humans are the only source of infection. Transmission usually is by direct or close contact with contaminated secretions, which may involve droplets or fomites. Respiratory syncytial virus can persist on environmental surfaces for many hours and for a half-hour or more on hands. Infection among hospital personnel and others can occur by self-inoculation with contaminated secretions. Enforcement of infection control policies is important to decrease the risk of health care-related transmission of RSV. Health care-related spread of RSV to organ transplant recipients or patients with cardiopulmonary abnormalities or immunocompromised conditions has been associated with severe and fatal disease in children and adults.

Respiratory syncytial virus usually occurs in annual epidemics during winter and early spring in temperate climates. Spread among household and child care contacts, including adults, is common. The period of viral shedding usually is 3 to 8 days, but shedding may last longer, especially in young infants and in immunosuppressed individuals, in whom shedding may continue for as long as 3 to 4 weeks.

The **incubation period** ranges from 2 to 8 days; 4 to 6 days is most common.

DIAGNOSTIC TESTS: Rapid diagnostic assays, including immunofluorescent and enzyme immunoassay techniques for detection of viral antigen in nasopharyngeal specimens, are available commercially and generally are reliable. The sensitivity of these assays in comparison with culture varies between 53% and 96%, with most in the 80% to 90% range. As with all antigen detection assays, false-positive test results are more likely to occur at the beginning or end of the RSV season when the incidence of disease is low. Therefore, antigen detection assays should not be the solitary basis on which the beginning and end of monthly prophylaxis is determined.

Viral isolation from nasopharyngeal secretions in cell cultures requires 3 to 5 days, but results and sensitivity vary among laboratories, because methods of isolation are exacting and RSV is a labile virus. Experienced viral laboratory personnel should be consulted for optimal methods of collection and transport of specimens. Serologic testing of acute and convalescent serum specimens should not be used to confirm infection; in particular, the sensitivity of serologic diagnosis of infection is low among young infants. The polymerase chain reaction assay has been used for detection of RSV in clinical specimens but is not available commercially.

TREATMENT: Primary treatment is supportive and should include hydration, careful clinical assessment of respiratory status, including measurement of oxygen saturation, use of supplemental oxygen, suction of the upper airway, and if necessary, intubation and mechanical ventilation. Ribavirin has in vitro antiviral activity against RSV, but ribavirin aerosol treatment for RSV infection is not recommended routinely. Ribavirin therapy has been associated with a small but statistically significant increase in oxygen saturation during the acute infection in several small studies. However, a consistent decrease in need for mechanical ventilation, decrease in length of stay in the pediatric intensive care unit, or reduction in days of hospitalization among ribavirin recipients has not been demonstrated. The high cost, aerosol route of administration, concern about potential toxic effects among exposed health care professionals, and conflicting results of efficacy trials have led to controversy about the use of this drug. A decision about ribavirin administration should be made on the basis of the particular clinical circumstances and experience of the physician.

BETA-ADRENERGIC AGENTS. Beta-adrenergic agents are not recommended for routine care of first-time wheezing associated with RSV bronchiolitis. Some physicians elect to use bronchodilator therapy because of concern that reactive airway disease may be misdiagnosed as bronchiolitis. Repeat doses of an inhaled bronchodilator should be

continued only in the small number of infants with well-documented improvement in respiratory function soon after the first dose.

CORTICOSTEROIDS. In hospitalized infants with RSV bronchiolitis, corticosteroids are not effective and are not indicated.

ANTIMICROBIAL AGENTS. Antimicrobial agents rarely are indicated, because bacterial lung infection and bacteremia are uncommon in infants hospitalized with RSV bronchiolitis or pneumonia. Otitis media occurs in infants with RSV bronchiolitis, but oral antibiotic agents can be used if therapy for otitis media is necessary.

PREVENTION OF RSV INFECTIONS. Palivizumab, a humanized mouse monoclonal antibody that is administered intramuscularly, is available to reduce the risk of RSV hospitalization in high-risk children. Respiratory Syncytial Virus Immune Globulin Intravenous (RSV-IGIV), a hyperimmune, polyclonal globulin prepared from donors selected for high serum titers of RSV neutralizing antibody, no longer is available. Palivizumab is licensed for prevention of RSV lower respiratory tract disease in selected infants and children with chronic lung disease of prematurity (CLD [formerly called bronchopulmonary dysplasia]) or with a history of preterm birth (<35 weeks' gestation) or with congenital heart disease. Palivizumab is administered every 30 days, beginning in early November, with 4 subsequent monthly doses (total of 5 doses). The dose of palivizumab is 15 mg/kg, administered intramuscularly. Palivizumab is not effective in the treatment of RSV disease, and it is not approved for this indication.

Recommendations by the American Academy of Pediatrics for the use of palivizumab are as follows:

- Palivizumab prophylaxis should be considered for infants and children younger than 24 months of age with chronic lung disease of prematurity who have required medical therapy (supplemental oxygen, bronchodilator or diuretic or corticosteroid therapy) for CLD within 6 months before the start of the RSV season. Patients with more severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season. Data are limited regarding the effectiveness of palivizumab during the second year of life. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists.
- Infants born at 32 weeks of gestation or earlier may benefit from RSV prophylaxis, even if they do not have CLD. For these infants, major risk factors to consider include their gestational age and chronologic age at the start of the RSV season. Infants born at 28 weeks of gestation or earlier may benefit from prophylaxis during their first RSV season, whenever that occurs during the first 12 months of life. Infants born at 29 to 32 weeks of gestation may benefit most from prophylaxis up to 6 months of age. For the purpose of this recommendation, 32 weeks' gestation refers to an infant born on or before the 32nd week of gestation (ie, 32 weeks, 0 days). Once a child qualifies for initiation of prophylaxis at the

start of the RSV season, administration should continue throughout the season and not stop at the point an infant reaches either 6 months or 12 months of age.

- Although palivizumab has been shown to decrease the likelihood of hospitalization in infants born between 32 and 35 weeks of gestation (ie, between 32 weeks, 1 day and 35 weeks, 0 days), the cost of administering prophylaxis to this large group of infants must be considered carefully. Therefore, most experts recommend that prophylaxis should be reserved for infants in this group who are at greatest risk of severe infection and who are younger than 6 months of age at the start of the RSV season. Epidemiologic data suggest that RSV infection is more likely to lead to hospitalization for these infants when the following risk factors are present: child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease. However, no single risk factor causes a very large increase in the rate of hospitalization, and the risk is additive as the number of risk factors for an individual infant increases. Therefore, prophylaxis should be considered for infants between 32 and 35 weeks of gestation only if 2 or more of these risk factors are present. Passive household exposure to tobacco smoke has not been associated with an increased risk of RSV hospitalization on a consistent basis. Furthermore, exposure to tobacco smoke is a risk factor that can be controlled by the family of an infant at increased risk of severe RSV disease, and preventive measures will be far less costly than palivizumab prophylaxis. High-risk infants never should be exposed to tobacco smoke. In contrast to the well-documented beneficial effect of breastfeeding against many viral illnesses, existing data are conflicting regarding the specific protective effect of breastfeeding against RSV infection. High-risk infants should be kept away from crowds and from situations in which exposure to infected individuals cannot be controlled. Participation in group child care should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene. In addition, all high-risk infants and their contacts should be immunized against influenza beginning at 6 months of age.
- In the Northern hemisphere and particularly within the United States, RSV circulates predominantly between November and March. The inevitability of the RSV season is predictable, but the severity of the season, the time of onset, the peak of activity, and the end of the season cannot be predicted precisely. There can be substantial variation in timing of community outbreaks of RSV disease from year to year in the same community and between communities in the same year, even in the same region. These variations, however, occur within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States tend to experience the earliest onset of RSV activity, and Midwestern states tend to experience the latest. The duration of the season for western and northeast regions typically occurs between that noted in the South and the Midwest. In recent years, the national median duration of the RSV season has been 15 weeks and even in the South, with a seasonal duration of 16 weeks, the range is 13 to 20 weeks. Results from clinical trials indicate that palivizumab trough serum concentrations >30 days after the fifth dose will be well

above the protective concentration for most infants. If the first dose is administered in November, 5 monthly doses of palivizumab will provide substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and end. Changes from this recommendation of 5 monthly doses require careful consideration of the benefits and costs.

- Children who are 24 months of age or younger with hemodynamically significant cyanotic and acyanotic congenital heart disease will benefit from palivizumab prophylaxis. Decisions regarding prophylaxis with palivizumab in children with congenital heart disease should be made on the basis of the degree of physiologic cardiovascular compromise. Children younger than 24 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:
- Infants who are receiving medication to control congestive heart failure
- Infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart disease

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of palivizumab (15 mg/kg) should be considered as soon as the patient is medically stable.

The following groups of infants are **not** at increased risk of RSV and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy

Dates for initiation and termination of prophylaxis should be based on the same considerations as for high-risk preterm infants.

- Palivizumab prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, children with severe immunodeficiencies (eg, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) may benefit from prophylaxis.
- Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. However, insufficient data exist to determine the effectiveness of palivizumab use in this patient population.
- If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should continue through the

RSV season. This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often cocirculates in a community.

- Physicians should arrange for drug administration within 6 hours after opening a vial of palivizumab, because this biological product does not contain a preservative.
- Respiratory syncytial virus is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. In high-risk hospitalized infants, the major means to prevent RSV disease is strict observance of infection control practices, including prompt isolation of RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric intensive care unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of nosocomial disease.
- Palivizumab does not interfere with response to vaccines.

ISOLATION OF THE HOSPITALIZED PATIENT: In addition to standard precautions, contact precautions are recommended for the duration of RSV-associated illness among infants and young children, including patients treated with ribavirin. The effectiveness of these precautions depends on compliance and necessitates scrupulous adherence to appropriate hand hygiene practices. Patients with RSV infection should be cared for in single rooms or placed in a cohort.

CONTROL MEASURES: The control of nosocomial RSV transmission is complicated by the continuing chance of introduction through infected patients, staff, and visitors. During the peak of the RSV season, many infants and children hospitalized with respiratory tract symptoms will be infected with RSV and should be cared for with contact precautions (see Isolation of the Hospitalized Patient, p 565). Early identification of RSV-infected patients (see Diagnostic Tests, p 561) is important so that appropriate precautions can be instituted promptly. During large outbreaks, a variety of measures have been demonstrated to be effective, including the following: (1) laboratory screening of symptomatic patients for RSV infection; (2) cohorting infected patients and staff; (3) excluding visitors with respiratory tract infections; (4) excluding staff with respiratory tract illness or RSV infection from caring for susceptible infants; and (5) use of gowns, gloves, goggles, and perhaps masks.

A critical aspect of RSV prevention among high-risk infants is education of parents and other caregivers about the importance of decreasing exposure to and transmission of RSV. Preventive measures include limiting, where feasible, exposure to contagious settings (eg, child care centers) and emphasis on hand hygiene in all settings, including the home, especially during periods when the contacts of high-risk children have respiratory infections.

Related text in Red Book:

Preterm and Low Birth Weight Infants

Red Book 2006: 67-69. [Extract] [Full Version]

American Indian/Alaska Native Children

Red Book 2006: 87-90. [Extract] [Full Version]

This topic has been referenced by these articles:

- Uzel, G., Premkumar, A., Malech, H. L., Holland, S. M. (2000). Respiratory Syncytial Virus Infection in Patients With Phagocyte Defects. *Pediatrics* 106: 835-837 [Abstract] [Full Version]
- Gavin, P. J., Katz, B. Z. (2002). Intravenous Ribavirin Treatment for Severe Adenovirus Disease in Immunocompromised Children. *Pediatrics* 110: e9-9 [Abstract] [Full Version]
- Bockova, J., O'Brien, K. L., Oski, J., Croll, J., Reid, R., Weatherholtz, R. C., Santosham, M., Karron, R. A. (2002). Respiratory Syncytial Virus Infection in Navajo and White Mountain Apache Children. *Pediatrics* 110: e20-20 [Abstract] [Full Version]
- Titus, M. O., Wright, S. W. (2003). Prevalence of Serious Bacterial Infections in Febrile Infants With Respiratory Syncytial Virus Infection. *Pediatrics* 112: 282-284 [Abstract] [Full Version]
- Thatayatikom, A., Liu, A. H. (2005). Vascular Endothelial Growth Factor (VEGF) Induces Remodeling and Enhances Th2-Mediated Sensitization and Inflammation in the Lung. *Pediatrics* 116: 556-557 [Full Version]
- Choudhuri, J. A., Ogden, L. G., Ruttenber, A. J., Thomas, D. S.K., Todd, J. K., Simoes, E. A.F. (2006). Effect of Altitude on Hospitalizations for Respiratory Syncytial Virus Infection. *Pediatrics* 117: 349-356 [Abstract] [Full Version]
- Pinto, R. A., Arredondo, S. M., Bono, M. R., Gaggero, A. A., Diaz, P. V. (2006). T Helper 1/T Helper 2 Cytokine Imbalance in Respiratory Syncytial Virus Infection Is Associated With Increased Endogenous Plasma Cortisol. *Pediatrics* 117: e878-e886 [Abstract] [Full Version]

Synagis

NDC USAGE for synagis from 08/01/05 to 05/01/06 for Program All			
NDC Code	**Rx Num**	**Total Reimb Amt**	**Label Name**
60574411101	141	$201,775.83	SYNAGIS 100 MG VIAL
60574411201	83	$59,432.00	SYNAGIS 50 MG VIAL
60574411301	35	$48,549.18	SYNAGIS 100 MG/1 ML VIAL
60574411401	20	$33,700.00	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	279	$343,457.01	
60 patients/30 physicians			

NDC USAGE for synagis from 08/01/06 to 04/27/07 for Program All			
NDC Code	**Rx Num**	**Total Reimb Amt**	**Label Name**
60574411301	237	$362,015.86	SYNAGIS 100 MG/1 ML VIAL
60574411401	114	$85,310.76	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	351	$447,326.62	
84 patients/27 physicians			

HEALTH INFORMATION DESIGNS

Synagis Prescribers 2006-2007 Season

Prescribing Physicians	Patients per Physician	Rx Num	City
11577	8	42	Bismarck
11867	8	36	Bismarck
18949	15	75	Bismarck
15372	1	6	Cando
10421	3	11	Dickinson
18565	2	4	Dickinson
11974	1	4	Fargo
13079	3	4	Fargo
13117	1	4	Fargo
13203	1	1	Fargo
13724	1	4	Fargo
14362	1	2	Fargo
14687	1	4	Fargo
14760	1	4	Fargo
11327	4	19	Grand Forks
11815	3	4	Grand Forks
12520	5	13	Grand Forks
12539	1	2	Grand Forks
13147	9	35	Grand Forks
14379	1	7	Grand Forks
15647	3	6	Grand Forks
17626	6	29	Grand Forks
19515	1	2	Grand Forks
19655	2	2	Grand Forks
13561	1	7	Rugby
14103	1	1	Wahpeton
10919	2	19	Williston

HEALTH INFORMATION DESIGNS

ARB and Renin Inhibitor PA Form

Clear Fields

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 an ARB or Renin Inhibitor, must use and fail one ACE Inhibitor.

- Angiotensin II receptor antagonists: Hyzaar, Micardis, Micardis/HCT, Teveten, Teveten/HCT, Atacand, Atacand/HCT, Avapro, Avalide, Benicar, Benicar/HCT, Cozaar, Diovan, Diovan/HCT
- Renin Inhibitor: Tekturna

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

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

Qualifications for coverage:

☐ Failed ACE Inhibitor	Start Date:	Dose:
	End Date:	Frequency:

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Physician Signature: Date:

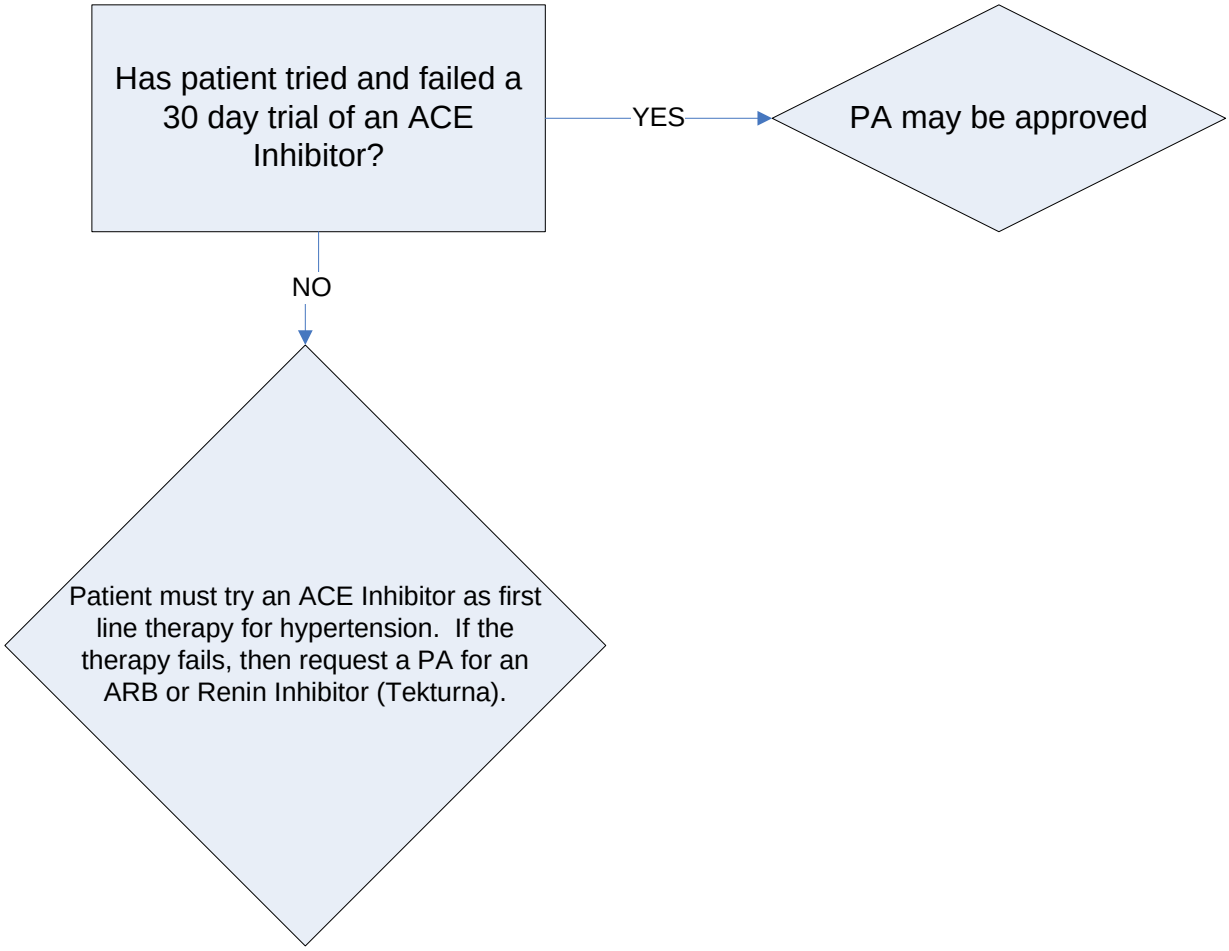
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
ARB and Renin Inhibitor (Tekturna) Authorization Criteria Algorithm



Xopenex Utilization from 01/01/06 to 02/26/07

Rx Num	Total Claim Cost	Label Name
187	$10,132.42	XOPENEX HFA 45 MCG INHALER

Xopenex Prescribers by City (scripts of 2 or more)

Prescribing Physicians	Patients per Physician	Rx Num	Location
11363	8	9	Bismarck
18949	2	6	Bismarck
10332	5	5	Bismarck
16461	3	5	Bismarck
12961	1	4	Bismarck
14254	3	9	Bismarck
14301	4	4	Bismarck
14311	4	9	Bismarck
14317	1	10	Bismarck
16763	1	4	Bismarck
17583	3	7	Bismarck
18113	2	2	Bismarck
18731	2	2	Bismarck
18975	4	4	Bismarck
15348	2	2	Bismarck
12861	1	2	Bismarck
10988	2	2	Bismarck
16167	2	2	Bismarck
17583	3	7	Bismarck
17616	2	2	Bismarck
16186	2	3	Dickinson
19751	1	3	Dickinson
11510	1	2	Fargo
12281	1	2	Grand Forks
13341	3	3	Harvey
14910	1	6	In State Provider
19810	2	2	Jamestown
17845	22	39	Minot
15227	1	2	Minot
12822	1	2	Minot
53168	11	11	Out of State Provider

Xopenex Utilization age 16 and below 01/01/06 to 02/26/07

Rx Number	Total Reimb Amt	Label Name
75	$4,084.52	XOPENEX HFA 45 MCG INHALER

Prescribers of age 16 and below Xopenex scripts 01/01/06 to 02/26/07 (scripts of 2 or more)

Prescribing Physicians	Patients per Physician	Rx Num	Location
17845	8	14	Trinity Health-Minot Immunology
11363	8	9	Medcenter Peds
53168	8	9	Out of State Provider
18949	2	6	Medcenter Peds
10332	5	5	Medcenter Peds
16461	3	5	Medcenter Peds
16186	2	3	Dickinson IM/Peds
12822	1	2	Minot
13341	2	2	Harvey Family Practice
16167	2	2	St. A's Family Practice
17583	2	2	St. A's Family Practice
17616	2	2	Medcenter Family Practice
19810	2	2	Jamestown

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xopenex HFA PA Form

Clear Fields

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 Albuterol HFA must use Proventil HFA as first line therapy.
__Note:__

- Proventil HFA does not require PA.

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth:	
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone:
City:	FAX:
State: Zip:	

REQUESTED DRUG: **XOPENEX HFA**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

☐ Failed Proventil HFA Start Date: Dose:
End Date: Frequency:

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Physician Signature: Date:

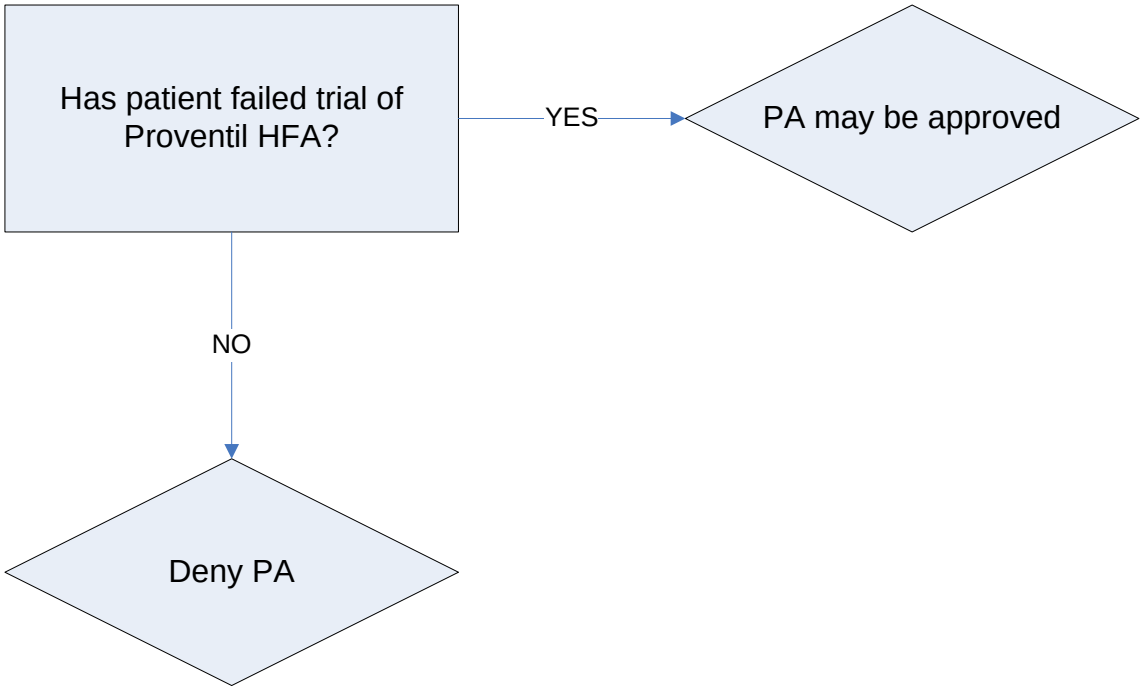
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Xopenex HFA Authorization Algorithm



HEALTH INFORMATION DESIGNS

Ketek Form

Clear Fields

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 will cover Ketek with a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae for patients 18 years and older.

ND Medicaid will cover Ketek for patients with an allergy to fluoroquinolones or tetracyclines.

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	
RECIPIENT DATE OF BIRTH:	RECIPIENT MEDICAID ID NUMBER:
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone:
City:	FAX:
State: Zip:	

REQUESTED DRUG:	**Requested Dosage:** (must be completed)

Qualifications for coverage:

- ❑ Community acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, (including multi-drug resistant isolates, Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae, or Mycoplasma pneumoniae) for patients 18 years and older.

*Please list fluoroquinolone or tetracycline that patient is allergic to:*_____

Physician Signature: Date:

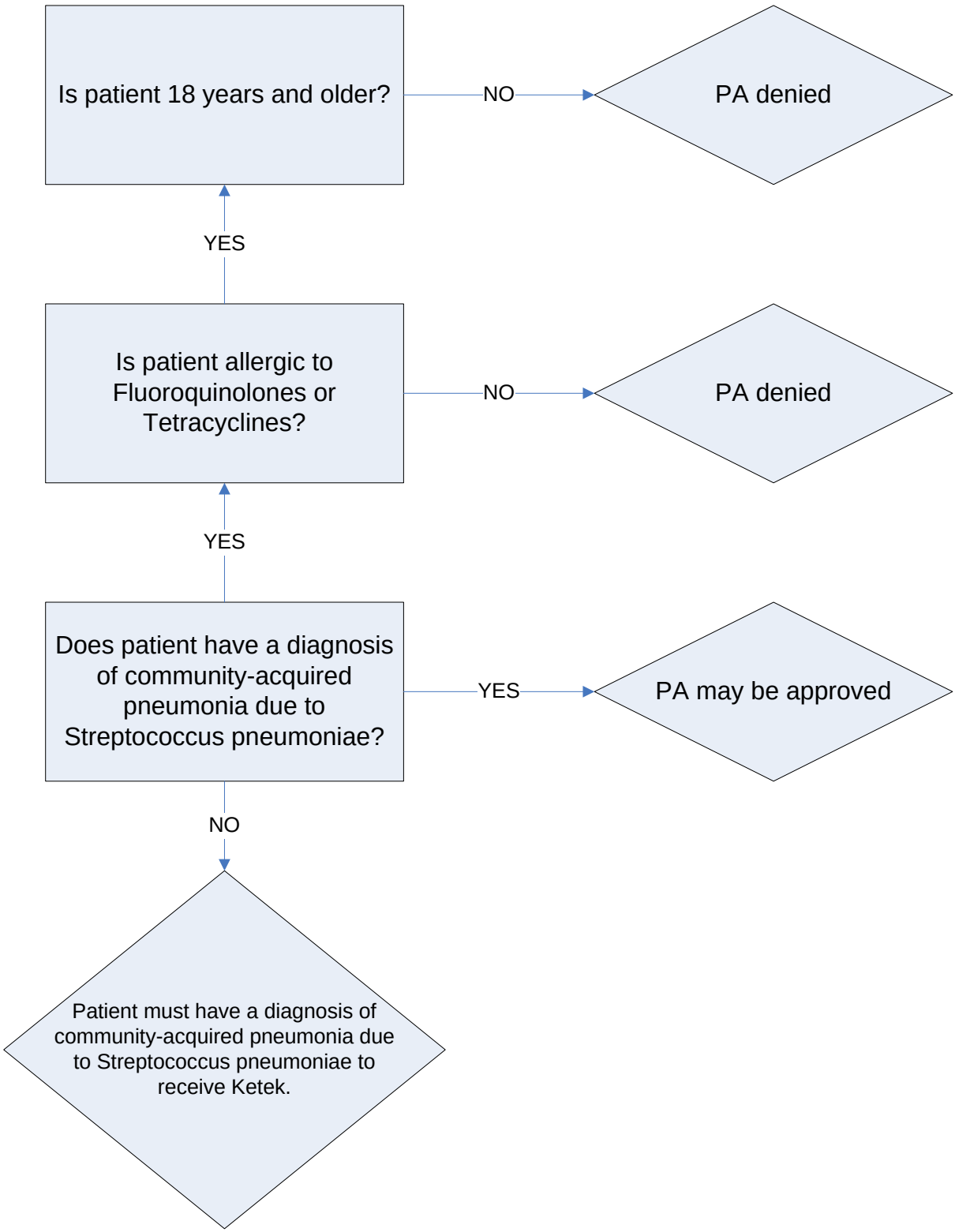
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Ketek Criteria Algorithm



North Dakota Century Code

SECTION 2 A new section to chapter 50-24.1 of the North Dakota Century Code is created and enacted as follows:

Medical assistance program management-The department of human services, with respect to the state medical assistance program, shall:
6. Review and develop recommendations regarding whether to require medical assistance providers to secure prior authorization for certain high-cost medical procedures.

2005 House Bill 1459 directed the Department to review expensive medical procedures for prior authorization. To be consistent with that direction, we will ask the DUR Board to review expensive medications for prior authorization. It is common practice through insurance and Medicaid agencies to set a level at which everything beyond that level requires prior authorization. These are typically put in as 'safety edits' in claims processing systems, but we are bringing it through the Board.

We must remember that new products are coming out continuously, therefore we will not limit our review to specific products, but we will determine a level for the 'safety edit' based on cost. It is good payer practice to know when and why these expensive products are being used. It assists with utilization review, disease management, and budget planning. Also, it protects from exposure to fraud, as many of these products are billed by out of state pharmacy providers and are prescribed by specialists from out of state medical practices.

Prescriptions Dispensed 1/1/06 thru 12/28/06 Amount Billed Greater Than $1000.00

NDC Number	NDC Name	Avg. Amt Billed	Avg. Amt Paid
59148001013	ABILIFY	$1,180.08	$810.78
49502069203	ACCUNEB	$1,498.10	$706.60
00944294004	ADVATE	$14,726.40	$14,723.40
00406007101	ANAGRELIDE HCL	$1,165.50	$175.60
60258044530	ANDEHIST DM NR	$4,785.20	$1,218.49
00088120806	ANZEMET	$1,177.39	$1,064.38
55513004601	ARANESP	$2,440.22	$2,281.66
00007323411	ARIXTRA	$3,365.90	$3,029.41
59627000103	AVONEX	$2,037.79	$1,278.00
00066057760	BENZAMYCIN PAK	$2,864.70	$2,575.99
50419052325	BETASERON	$1,681.67	$1,183.61
00087611142	CAFCIT	$1,544.80	$1,388.62
00006382210	CANCIDAS	$2,372.16	$745.91
60432023730	CARBAXEFED DM RF	$4,936.80	$961.40
44206041812	CARIMUNE NF	$1,881.00	$218.75
54482014508	CARNITOR	$1,697.99	$37.86
10019009801	CEFTRIAXONE	$1,164.27	$323.31
00781932895	CEFTRIAXONE NOVAPLUS	$1,153.60	$512.75
00004026001	CELLCEPT	$1,081.75	$949.16
63304095902	CEPHALEXIN	$1,801.80	$805.60
00172436060	CLOZAPINE	$1,565.50	$485.00
00078012705	CLOZARIL	$1,162.75	$1,040.86
65649010102	COLAZAL	$9,179.45	$8,259.81
39822061501	COLISTIMETHATE SODIUM	$2,517.43	$2,307.63
61570041451	COLY-MYCIN M	$3,550.00	$3,199.85
00088115330	COPAXONE	$1,655.06	$1,299.07
00004008694	COPEGUS	$1,819.03	$999.42
67919001101	CUBICIN	$3,424.02	$2,247.15
00074568216	DEPAKENE	$1,095.95	$454.20
00074621513	DEPAKOTE	$1,065.76	$883.18
45802042237	DESONIDE	$2,914.89	$1,157.60
51672127003	DESOXIMETASONE	$2,081.50	$1,674.20
58406042534	ENBREL	$1,983.54	$1,033.08
55513082301	EPOGEN	$1,930.29	$1,694.73
00378326694	ETOPOSIDE	$1,913.00	$1,720.55
00078047015	EXJADE	$6,711.60	$6,042.17
00013242691	FRAGMIN	$1,104.14	$1,025.16
99073012050	FREESTYLE	$2,764.50	$53.32
99073011001	FREESTYLE BLOOD GLUCOSE SYSTEM	$8,027.50	$72.10

99073013001	FREESTYLE LANCETS	$1,148.44	$12.48
00172444460	GABAPENTIN	$1,022.25	$238.25
00944262004	GAMMAGARD S/D	$1,279.00	$898.00
00013264681	GENOTROPIN	$4,296.08	$1,520.99
00013265802	GENOTROPIN MINIQUICK	$2,263.93	$1,835.02
00078043815	GLEEVEC	$3,780.66	$2,308.97
00002803101	GLUCAGON EMERGENCY KIT	$1,758.80	$1,656.48
63004773101	H.P. ACTHAR	$2,864.63	$2,777.60
00053813004	HELIXATE FS	$17,790.61	$8,802.33
00002751001	HUMALOG	$1,284.34	$278.34
00074379902	HUMIRA	$1,645.63	$1,306.60
00002873059	HUMULIN N PEN	$1,257.81	$110.28
00173052300	IMITREX	$1,258.34	$174.54
00173047800	IMITREX STATDOSE REFILL	$1,215.40	$1,089.16
67211034253	INNOHEP	$2,267.30	$1,964.15
00085117902	INTRON A	$1,881.98	$1,833.84
00006384371	INVANZ	$1,372.34	$970.52
66794000260	IPRATROPIUM BROMIDE	$1,238.30	$73.21
00310048230	IRESSA	$2,737.81	$156.52
00074679922	KALETRA	$1,213.54	$1,079.55
55513017728	KINERET	$1,435.53	$1,305.00
00026037230	KOGENATE FS	$7,464.80	$7,443.03
00004024126	KYTRIL	$1,674.67	$1,409.87
60505056202	LACTULOSE	$1,302.98	$33.98
00173063302	LAMICTAL	$1,275.05	$995.07
00173052700	LAMICTAL CD	$1,223.25	$1,105.50
00093571501	LAMOTRIGINE	$1,034.32	$778.48
49348091122	LANCETS	$2,194.10	$13.23
00088222033	LANTUS	$8,383.84	$450.24
00555048527	LEUCOVORIN CALCIUM	$1,268.35	$0.00
00045153005	LEVAQUIN LEVA-PAK	$1,731.25	$1,554.10
00173072100	LEXIVA	$1,394.76	$1,246.44
00115704001	LIPRAM-PN10	$1,590.08	$615.83
00409198530	LORAZEPAM	$1,760.00	$110.15
00075291501	LOVENOX	$2,817.16	$2,414.91
00300228201	LUPRON DEPOT-PED	$1,214.41	$551.27
00310032130	MERREM IV	$3,117.26	$2,150.24
00089020025	METROGEL-VAGINAL	$4,589.50	$4,589.50
52769046001	MONARC-M	$18,267.89	$18,165.68
00074202902	MORPHINE SULFATE	$1,776.00	$423.84
00015722618	NAFCILLIN SODIUM	$1,500.00	$544.57
49735011047	NEOCATE ONE +	$1,423.50	$1,423.50
55513019001	NEULASTA	$7,713.99	$7,364.17
55513092410	NEUPOGEN	$3,788.15	$3,039.68

00766145020	NICODERM CQ	$1,271.05	$79.56
00169770511	NORDITROPIN NORDIFLEX	$1,229.04	$745.74
00169750111	NOVOLOG	$1,968.00	$13.13
00074775329	NUTRIMIX W/ELECTROLYTES	$5,735.40	$24.12
50242002220	NUTROPIN AQ	$1,181.21	$2.06
50242004314	NUTROPIN AQ PEN CARTRIDGE	$2,020.80	$1,457.87
00168003760	NYSTATIN	$1,241.50	$501.61
00574030316	ORA-PLUS	$1,783.79	$0.00
00062125115	ORTHO TRI-CYCLEN LO	$1,021.51	$47.52
00093003301	OXYCODONE HCL	$1,308.99	$893.60
60951071070	OXYCODONE HYDROCHLORIDE	$1,763.30	$1,162.32
59011010710	OXYCONTIN	$1,217.28	$950.88
00045034260	PANCREASE MT 10	$1,168.31	$575.08
00045034660	PANCREASE MT 20	$1,395.07	$1,118.85
59767000102	PANCRECARB MS-8	$1,767.25	$1,176.07
00004035239	PEGASYS	$1,813.62	$1,640.58
00085127901	PEG-INTRON	$1,880.73	$1,481.57
00944047180	POLYGAM S/D	$1,521.29	$1,097.66
57599881401	PRECISION XTRA MONITOR	$6,479.60	$5,831.74
00300304613	PREVACID	$1,512.29	$54.32
00006351458	PRIMAXIN IV	$1,902.03	$489.04
59676034001	PROCRIT	$2,115.13	$1,972.21
00469061773	PROGRAF	$1,280.27	$1,012.24
00338049906	PROSOL	$1,233.06	$928.31
00008092355	PROTONIX	$1,728.00	$841.60
00186198904	PULMICORT RESPULES	$1,080.35	$196.16
50242010040	PULMOZYME	$2,088.05	$1,637.62
00008104105	RAPAMUNE	$1,051.99	$947.54
00085135105	REBETOL	$2,142.86	$1,112.27
44087002203	REBIF	$1,830.78	$1,670.52
00069419068	REVATIO	$1,164.03	$951.11
49884085694	RIBASPHERE	$1,022.95	$1,005.20
59930152301	RIBAVIRIN	$1,473.91	$966.77
50458030811	RISPERDAL CONSTA	$1,139.81	$754.20
00004196401	ROCEPHIN	$1,226.60	$967.60
44087108801	SAIZEN	$1,544.51	$205.69
00078018325	SANDOSTATIN	$1,390.05	$1,340.40
00310027460	SEROQUEL	$1,419.35	$1,150.24
00006384130	SINGULAIR	$3,385.21	$2,930.73
60793013601	SKELAXIN	$1,373.59	$84.56
00703951403	SMZ-TMP CONCENTRATE	$1,053.91	$744.95
00338004904	SODIUM CHLORIDE	$1,163.33	$335.98
50924097110	SOFTCLIX LANCETS	$1,279.00	$14.16
10631058677	SOTRET	$1,168.61	$767.60

00003052411	SPRYCEL	$3,639.34	$3,216.06
00069098030	SUTENT	$6,981.71	$5,645.17
60574411301	SYNAGIS	$1,717.12	$1,441.52
50242006401	TARCEVA	$3,394.11	$2,865.44
00083001976	TEGRETOL	$1,145.85	$87.14
00085125901	TEMODAR	$2,844.02	$1,743.92
59572020594	THALOMID	$3,454.40	$2,745.62
58468184904	THYROGEN	$3,207.84	$1,635.85
00029657126	TIMENTIN	$1,508.00	$414.37
53905006501	TOBI	$3,498.74	$2,673.94
00703941601	TOBRAMYCIN SULFATE	$1,022.44	$493.85
00045064565	TOPAMAX	$1,075.15	$738.41
66215010106	TRACLEER	$6,100.19	$3,443.98
57664037718	TRAMADOL HCL	$1,159.69	$58.40
00008536002	TYGACIL	$1,103.71	$596.67
58914001810	ULTRASE MT18	$1,115.46	$355.39
58914000450	ULTRASE MT20	$1,389.85	$1,147.37
00004003822	VALCYTE	$2,594.54	$2,296.09
00049318030	VFEND	$2,028.07	$1,769.75
00004110150	XELODA	$1,797.49	$1,572.85
50242004062	XOLAIR	$1,069.97	$207.31
62161000820	XYREM	$1,013.70	$912.85
00069314019	ZITHROMAX	$1,551.79	$1,400.95
00173044700	ZOFRAN	$1,916.96	$1,528.67
00173056900	ZOFRAN ODT	$1,841.59	$652.36
00310095130	ZOLADEX	$1,416.05	$1,273.58
00310021020	ZOMIG	$9,404.05	$108.87
00002442030	ZYPREXA	$1,264.99	$1,114.96
00002445685	ZYPREXA ZYDIS	$1,464.97	$1,227.69
00009513502	ZYVOX	$1,782.91	$1,521.70

NDC USAGE for nd-growthhormone from 06/01/06 to 04/24/07 for Program All
Claims Type: Medicaid

NDC Code	Rx Num	Total Reimb Amt	Label Name
13264681	5	$1,012.52	GENOTROPIN 13.8 MG CARTRIDGE
13264694	4	$429.28	GENOTROPIN 13.8 MG CARTRIDGE
13265102	8	$6,582.41	GENOTROPIN MINIQUICK 0.6 MG
13265802	8	$21,625.06	GENOTROPIN MINIQUICK 2 MG
44087108801	1	$37.97	SAIZEN 8.8 MG VIAL
50242004314	2	$178.51	NUTROPIN AQ PEN CARTRIDGE
TOTAL	28	$29,865.75	6 recipients/2 prescribers

Growth Hormone PRIOR AUTHORIZATION

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Clear Fields

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

ND Medicaid requires that patients receiving Growth Hormone meet one of the criteria below:

- **Growth Hormone Deficiency in children and adults with a history of hypothalamic pituitary disease**
- **Short stature associated with chronic renal insufficiency before renal transplantation**
- **Short stature in patients with Turners Syndrome (TS) or Prader-Willi Syndrome (PWS)**
- **Human Immunodeficiency Virus (HIV) associated wasting in adults**

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG:	**Requested Dosage:** (must be completed)

Qualifications for coverage:

Criteria met:	Diagnosis Date: Drug:	Dose: Frequency:

Physician Signature: Date:

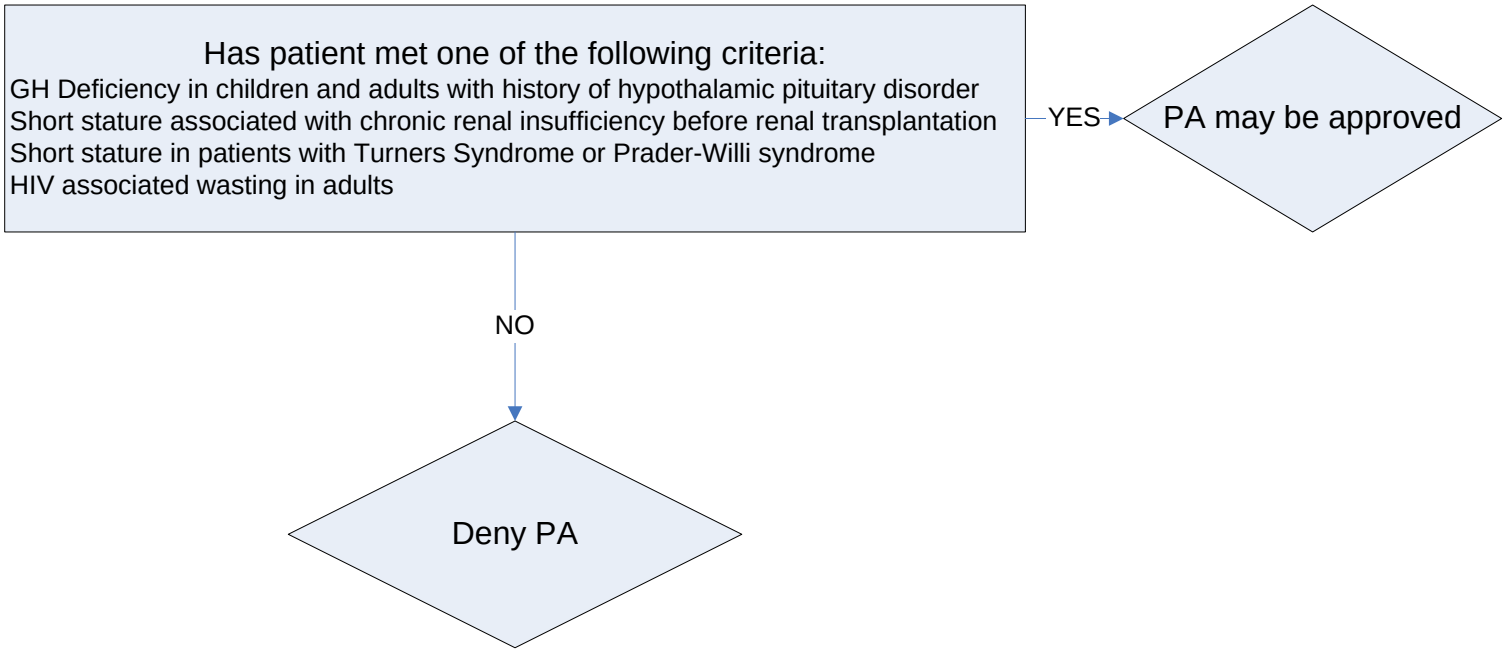
Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Growth Hormone Authorization Algorithm



NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2007

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

1. Elidel / Therapeutic Appropriateness _____ _____

Alert Message: The topical calcineurin inhibitor, Elidel (pimecrolimus), is indicated as second-line therapy for the short-term, non-continuous chronic treatment of mild to moderate atopic dermatitis in patients who are unresponsive or intolerant to other agents. Rare cases of malignancy (i.e., skin cancer and lymphoma) have been reported in patients treated with topical pimecrolimus. Application should be limited to the areas affected with atopic dermatitis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Pimecrolimus		High to Very High Potency Topical Corticosteroids
		Augmented Betamethasone
		Clobetasol
		Diflorasone
		Halobetasol
		Amcinonide
		Betamethasone
		Desoximetasone
		Fluocinolone
		Fluocinonide
		Halcinonide
		Triamcinolone

Day Supply: 20 days in current 90 days
Age Range: 0 – 999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006. Novartis Pharmaceuticals Corp.

2. Protopic / Therapeutic Appropriateness _____ _____

Alert Message: The topical calcineurin inhibitor, Protopic (tacrolimus), is indicated as second-line therapy for the short-term, non-continuous chronic treatment of moderate to severe atopic dermatitis in patients who are unresponsive or intolerant to other agents. Rare cases of malignancy (i.e., skin cancer and lymphoma) have been reported in patients treated with topical tacrolimus. Application should be limited to the areas affected with atopic dermatitis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Tacrolimus		Very High Potency Topical Corticosteroids
		Augmented Betamethasone
		Clobetasol
		Diflorasone
		Halobetasol
		Amcinonide
		Betamethasone
		Desoximetasone
		Fluocinolone
		Fluocinonide
		Halcinonide
		Triamcinolone

Day Supply: 20 days in current 90 days
Age Range: 0 – 999 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.

Recommendations	*Approved*	*Rejected*

3. Protopic & Elidel / Therapeutic Appropriateness (AGE) _____ _____

Alert Message: The topical calcineurin inhibitors, Protopic (tacrolimus) and Elidel (pimecrolimus), are not recommended for use in children less than 2 years of age. The long-term safety and effects of these agents on the developing immune system are unknown.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C
Tacrolimus		
Pimecrolimus		

Age Range: 0 – 1 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

4. Protopic / Therapeutic Appropriateness (AGE) _____ _____

Alert Message: The use of Protopic 0.1% ointment (topical tacrolimus) is not recommended in children less than 15 years of age. The 0.03% tacrolimus ointment is approved for use in children ages 2 to 15. Application should be limited to areas affected with atopic dermatitis. If signs and symptoms have not resolved within 6 weeks patient should be re-examined to confirm diagnosis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C
Tacrolimus 0.1%		

Age Range: 2-15 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.

5. Elidel / Immunocompromised Patients _____ _____

Alert Message: Elidel (topical pimecrolimus) should not be used in immunocompromised adults and children. These patients are at risk for increased systemic exposure and adverse effects of pimecrolimus.
Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Drug/Disease:

Util A	Util B	Util C
Pimecrolimus	HIV Diagnosis	
	Antiretrovirals	
	Transplant Diagnoses	
	Immunosuppressive Agents	

Age Range: 0-999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

Recommendations	*Approved*	*Rejected*

6. Protopic / Immunocompromised Patients _____ _____

Alert Message: Protopic (topical tacrolimus) should not be used in immunocompromised adults and children. These patients are at risk for increased systemic exposure and adverse effects of tacrolimus.
Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Drug/Disease:

Util A	Util B	Util C
Tacrolimus	HIV Diagnosis	
	Antiretrovirals	
	Transplant Diagnosis	
	Immunosuppressive Agents	

Age Range: 0-999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

7. Topical Immunomodulators / Therapeutic Duplications _____ _____

Alert Message: Therapeutic duplication of topical immunomodulator agents may be occurring.
Conflict Code:
Drug/Disease:

Util A	Util B	Util C
Tacrolimus		
Pimecrolimus		

References:
Facts & Comparisons, 2006 Updates.
Micromedex Healthcare Series, DRUGDEX Drug Evaluations, 2007.

8. Lisdexamfetamine / High Dose _____ _____

Alert Message: Vyvanse (lisdexamfetamine) may be over-utilized. The manufacturer's recommended maximum dose for children is 70 mg daily. Doses greater than 70 mg have not been studied in children.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Max Dose: 70 mg/day
Age Range 6 – 12 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

9. Lisdexamfetamine / Therapeutic Appropriateness _____ _____

Alert Message: Vyvanse (lisdexamfetamine) is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 to 12 years of age. This agent has not been studied in children 3 to 5 years of age. Amphetamines are not recommended for children under 3 years of age.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Age Range: 3 – 5 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

Criteria Recommendations *Approved* *Rejected*

10. Aliskiren / Pregnancy / Pregnancy Negating _____ _____

Alert Message: When pregnancy is detected Tekturna (aliskiren) should be discontinued as soon as possible. Aliskiren is a direct renin inhibitor and drugs acting directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Aliskiren is FDA pregnancy category C during the first trimester and pregnancy category D during the second and third trimesters.
Conflict Code: MC – Drug (Actual) Disease Precaution (Black Box Warning)
Drugs/Disease:

Util A	Util B	Util C (Negating)
Aliskiren	Pregnancy	Miscarriage
		Delivery
		Abortion

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

11. Aliskiren / High Dose _____ _____

Alert Message: Tekturna (aliskiren) may be over-utilized. The usual recommended starting dose is 150 mg once daily but may be increased to 300 mg if blood pressure is not adequately controlled. Doses above 300 mg have not increased the blood pressure response but have increased the rate of diarrhea.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Aliskiren		

Max Dose: 300 mg/day
References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

12. Aliskiren / Severe Renal Impairment _____ _____

Alert Message: Tekturna (aliskiren) should be used with caution in patients with severe renal impairment (GFR < 30mL/min), a history of dialysis, nephrotic syndrome or renovascular hypertension. Drugs acting on the renin-angiotensin system have the potential to increase serum creatinine and blood urea nitrogen.
Conflict Code: MC – Drug/Drug or Drug/Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Severe Renal Impairment	Nephrotic Syndrome
	Lanthanum	Renovascular Hypertension
	Sevelamer	Dialysis
	Paricalcitol	
	Doxercalciferol	
	Calcitriol	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

13. Aliskiren / ACEIs / Diabetes _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) and an ACE inhibitor in patients with diabetes may result in increased serum potassium levels. Routine monitoring of electrolytes and renal function is indicated in this population.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Inclusive)	
Aliskiren	ACE Inhibitors	Diabetes	Dipeptidyl Peptidase-4 Inhibitor
		Insulin	Biguanide
		Sulfonylureas	Meglitinides
		Amylin Analog	Thiazolidinediones
		Incretin Mimetic	
		Alpha-Glucosidase Inhibitors	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

14. Aliskiren / Furosemide _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with furosemide has been shown to significantly reduce the blood concentrations of furosemide. Co-administration of these agents resulted in a decrease in the AUC and Cmax of furosemide by 30% and 50%, respectively. The effects of furosemide may be diminished after starting aliskiren.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Furosemide	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

15. Aliskiren / Ketoconazole _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with ketoconazole may result in elevated aliskiren plasma levels due to inhibition of aliskiren CYP 3A4 mediated metabolism by ketoconazole. Co-administration of aliskiren with ketoconazole 200 mg twice daily has been shown to increase the plasma levels of aliskiren approximately 80%. A 400mg once-daily dose has not been studied but would be expected to increase aliskiren levels further.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Ketoconazole	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.
The Medical Letter on Drugs & Therapeutics, Volume 49 (Issue 1258), April 2007.

16. Pioglitazone / Therapeutic Appropriateness _____ _____

Alert Message: Pioglitazone-containing products (Actos/ActoPlusMet/Duetact) may increase the risk of fractures in female patients. Analysis of clinical trial data revealed an increased incidence of fractures in female patients taking long-term pioglitazone therapy as compared to females taking a comparator (placebo or active). Consider the risk of fractures when initiating or treating female, type 2 diabetic patients with pioglitazone.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Pioglitazone		

Gender: Female
References:
MedWatch – The FDA Safety Information and Adverse Event Reporting Program, 2007.

17. Methadone / Therapeutic Appropriateness _____ _____

Alert Msg: Methadone can cause significant toxicities. Vigilance is necessary during treatment initiation, dose titration, and drug conversion from other opioids to methadone. It is critical to understand the pharmacokinetics of methadone when converting patients to methadone. Methadone's half-life (8-59 hours) is longer than its duration of action (4-8 hours). Incomplete cross-tolerance makes conversion complex and does not eliminate the possibility of overdose.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Methadone		

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