ODJFS P&T Committee Meeting Minutes

Rhodes State Office Tower, Multipurpose Room, 30 E. Broad St., Columbus, OH 43215

Committee members present: Susan Baker, APN; Suzanne Eastman, RPh; Michael Howcroft, RPh; Cheryl Huffman, MD; Robert Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Mary Jo Welker, MD

ACS staff present: Stephanie Levine, PharmD, Clinical Manager

Approximately 50 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

1) Interested party presentations
   No requests for presentations were received.

2) Old Business
   a) Dr. Huffman said that she has had difficulty with Medicaid managed care plans (MCP) approving prior authorization requests for attention deficit hyperactivity disorder (ADHD) medications. Some MCPs require maximum doses on two different drugs before a non-preferred drug can be prescribed, and children under age 6 will only be approved for immediate-release generic Adderall. This product has been in short supply and not available at pharmacies, but the MCPs have not approved brand Adderall or any other alternatives.
   b) Follow-up on questions from P&T Committee at previous meetings
      i) Utilization of Intuniv, Kapvay, clonidine, guanfacine
         Dr. Levine presented the proportion of prescriptions for clonidine and guanfacine for adults vs. children. Utilizers of immediate-release clonidine and guanfacine are more likely to be under age 18, indicating these may be used for ADHD rather than cardiovascular conditions. ACS and ODJFS will continue to review utilization of Kapvay and Intuniv to see if there has been a change in utilization patterns of atypical antipsychotics since these agents were added as preferred agents on the preferred drug list (PDL)
      ii) Utilization of Plavix, Effient, Brilinta
         Dr. Levine presented the proportion of utilization of these drugs in January through March 2012. Only two claims were paid for Effient, and 6,354 claims for Plavix. The availability of generic Plavix will significantly decrease expenditures in this category.

3) New Business:
   a. PDL New Drug: Bydureon (exenatide extended-release) injectable suspension, Amylin. Amylin presented clinical information.
      Ms. Eastman asked the Amylin representative if the recommendation is to use short-acting Byetta before prescribing Bydureon, or to use Bydureon first. The representative from Amylin responded that the pharmacokinetic profile of Bydureon provides fewer adverse reactions.

Dr. Welker asked about the cost of twice-daily Byetta plus pen needles in relation to Bydureon. Ms. Scott replied that Bydureon is more expensive than Byetta, and in about the same price range as Victoza. The Amylin representatives said that Bydureon is priced between the two doses of Victoza, but that about 65% of Victoza utilization is at the higher dose so Bydureon may represent a savings. Dr. Hunter asked if compliance is enhanced with a once-weekly product. The Amylin representatives replied that patient preference is for a weekly product. Dr. Levine gave the recommendation for non-preferred status. All incretin mimetics require step therapy (any oral hypoglycemic or insulin); the recommendation is that Victoza and Byetta be tried before Bydureon.
The Committee voted 6 to 1 in favor of Bydureon being preferred along with Byetta and Victoza. Ms. Scott was the dissenting vote.

b. Proposed new drug classes and criteria for PDL
Preparation for PDL discussion at 6/27/12 meeting
Proposed changes:

1. Step Therapy / Generics First / Three-Tier System
   Presentation attached. Ms. Scott presented a "step through generic" proposal for the PDL. The goal of the PDL is to lower costs by encouraging the use of lower-cost drugs, including generic drugs, and to receive supplemental rebates from manufacturers. ODJFS is suggesting that in many PDL drug classes, a three-tier system can be implemented that would require the first drug prescribed to be a preferred generic drug, then if necessary a preferred brand drug can be approved through the SmartPA system, then finally a non-preferred drug could be used. Consumer co-payments would remain the same, $0 for preferred generics, $2 for preferred brands, and $3 for non-preferred drugs. A hypothetical historical example of ACE inhibitors available in 2005 (when about half of the drugs were brand name) was reviewed. ODJFS staff have discussed this proposal with several manufacturer representatives and received positive feedback.
   The P&T Committee discussed that this proposal may not be appropriate for all drug classes, and some patients may need to be grandfathered. Further details will be discussed for each drug class at the next meeting.

Ms. Scott presented proposals for new and re-named PDL classes. Details of the proposed renamed and new PDL classes are attached.

2. Renamed class – Gastroprotective NSAIDs
   Proposal to change the current COX-2 and PPI/NSAID PDL classes into a gastroprotective NSAIDs class encompassing four agents.
3. Renamed class – Oral Anticoagulant
   Proposal to change the Platelet Aggregation Inhibitors class to Oral Anticoagulants, removing Aggrenox, cilostazol, dipyridamole, and ticlopidine and adding Pradaxa, warfarin, and Xarelto.
4. New class – antiarrhythmics
   The P&T Committee recommended a trial of one preferred agent for 30 days.
5. New class – Pulmonary Arterial Hypertension Agents

The P&T Committee recommended a trial of two oral agents for 30 days each before approving an inhaled agent, and specific clinical criteria for IV agents. The committee asked if there were patients receiving IV and inhalation agents and if so could it be determined who is receiving the two formulations. Ms Scott stated there were claims for IV and inhalation.

6. New class – Neuropathic Pain Agents
7. New class – Restless Legs Syndrome Agents
8. New class – Topical Agents: Corticosteroids
   The P&T Committee discussed a time limit on authorizations for higher-potency agents, the need to look at disease severity and other treatments when prescribing, as well as a history of approvals and refills obtained. The committee requested a history of utilization of all the agents.
9. Reapproval criteria for Growth Hormones
   The P&T Committee noted that the proposed re-approval criteria depended on information that was not requested at the initial approval. ODJFS and ACS will recommend additional criteria for initial approval of growth hormones and reapproval criteria at the next meeting.

The P&T Committee will meet the second Wednesday of January, April, and October, and the last Wednesday in June. Upcoming meetings are scheduled for:
June 27, 2012
October 10, 2012
January 9, 2013
April 10, 2013

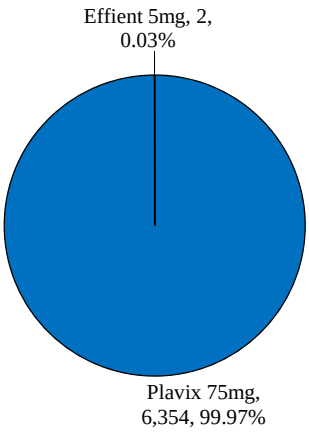
Following the meeting, ODJFS determined that committee recommendation of Bydureon as a preferred agent will be accepted.

Ohio Health Plans

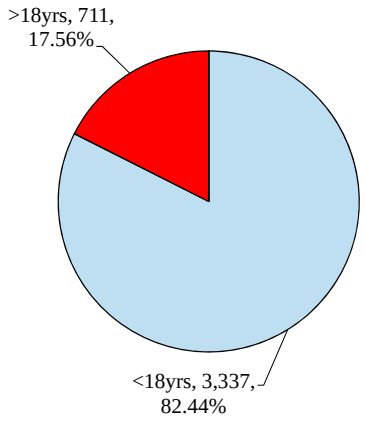
Utilization Updates

Stephanie Levine, PharmD
ACS Clinical Manager

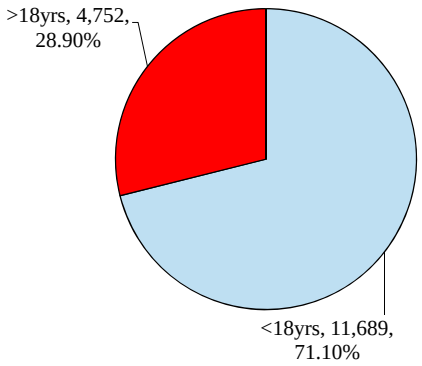
Platelet Aggregation Inhibitors : Market Share, 1Q12



Market Share for Guanfacine, 1Q12



Market Share for Clonidine, 1Q12



Ohio | Department of Job and Family Services
John R. Kasich, Governor
Michael B. Colbert, Director

Proposed Change to the Ohio Medicaid Preferred Drug List: Step Through Generic

Pharmacy & Therapeutics Committee
April 11, 2012

Preferred Drug List: Overview

- Preferred drugs chosen for clinical superiority and/or financial considerations
- Goals of the PDL:
  - Ensure high quality prescribing to improve health outcomes
  - Reduce costs
    - Drive prescribing to lower-cost drugs
    - Receive rebates from manufacturers

Market Changes

- Large number of new generic approvals in last several years
  - Statins
  - Antipsychotics
  - Angiotensin Receptor Blockers (ARB)
  - Alzheimer's
  - Anti-migraine
  - Osteoporosis
  - Benign Prostatic Hyperplasia (BPH)
  - Many more

Proposal: "Step Through Generic"

- Similar to multi-tier commercial plans
- Start patient on generic
  - Preferred brand may be approved after trial on generic
  - Non-preferred drug may be approved after trial on a preferred generic and a preferred brand
- Copays remain the same
  - $0 for preferred generics
  - $2 for preferred brands
  - $3 for non-preferred drugs (brand or generic)

Example: ACE Inhibitors in 2005

- 10 Available products:
  - Accupril® (quinapril)
  - Aceon® (perindopril)
  - Altace® (ramipril)
  - Benazepril (generic of Lotensin®)
  - Captopril (generic of Capoten®)
  - Enalapril (generic of Vasotec®)
  - Lisinopril (generic of Zestril®, Prinivil®)
  - Mavik® (trandolapril)
  - Monopril® (fosinopril)
  - Univasc® (moexipril)

Example: ACE Inhibitors in 2005 Indications

Indications √= FDA approved X = Unlabeled	**Benazepril**	**Captopril**	**Enalapril**	**Fosinopril**	**Lisinopril**	**Moexipril**	**Perindopril**	**Quinapril**	**Ramipril**	**Trandolapril**
Diabetic nephropathy	X	√	X		X				X	
Heart failure	X	√	√	√	√			√	√	√
Hypertension	√	√	√	√	√	√	√	√	√	√
Pediatric hypertension		X						X		
Improve survival post-MI					√					
Left ventricular dysfunction, post-MI		√								√
Left ventricular dysfunction, asymptomatic			√							
Nondiabetic nephropathy	X								X	
Reduce risk of MI, stroke, and death from cardiovascular causes									√	
Reduce risk of nonfatal MI or cardiovascular mortality							√			

Table adapted from Facts & Comparisons® eAnswers, Wolters Kluwer Health, Inc.

Example: ACE Inhibitors in 2005

- Dosing schedules
  - Once daily: Aceon®, lisinopril, Mavik®, Monopril®
  - Once or twice daily: Altace®, benazapril, Univasc®
  - Twice daily: Accupril®, enalapril
  - Three times daily: captopril
- Other Considerations
  - Dosage changes for renal impairment, hepatic impairment, children, elderly
  - Take with or without food

Actual 2005 PDL

NO PA REQUIRED "PREFERRED"	**PA REQUIRED**
BENAZEPRIL CAPTOPRIL ENALAPRIL LISINOPRIL	ACCUPRIL® ACEON® ALTACE® MAVIK® MONOPRIL® UNIVASC®

Possible "Step Through Generic" PDL

NO PA REQUIRED "PREFERRED" GENERICS	STEP THERAPY REQUIRED "PREFERRED" BRANDS	PA REQUIRED
BENAZEPRIL CAPTOPRIL ENALAPRIL LISINOPRIL	ALTACE® MAVIK®	ACCUPRIL® ACEON® MONOPRIL® UNIVASC®

Potential Drug Classes for "Step Through Generic" Strategy

- Analgesics
  - Gout
  - Opioids
- Blood Agents
  - Heparin-Related
  - Oral Anticoagulants
- Cardiovascular
  - ACE Inhibitors
  - ARBs
  - Alpha-Beta
- Cardiovascular
  - Antiarrhythmic
  - Beta Blockers
  - Calcium Channel Blockers
  - Lipotropics
  - Pulmonary Arterial Hypertension
  - Sympatholytic Antihypertensives

Potential Drug Classes for "Step Through Generic" Strategy

- CNS
  - Alzheimer's
  - Anti-Migraine
  - Antidepressants
  - Antipsychotics
  - ADHD
  - Muscle Relaxants
  - Parkinson's
  - RLS
  - Sedative-Hypnotics
  - Smoking Deterrents
- Endocrine
  - Oral Hypoglycemics
  - Estrogens
  - Osteoporosis
- Gastrointestinal
  - Anti-Emetic
  - Proton Pump Inhibitors
  - Ulcerative Colitis

Potential Drug Classes for "Step Through Generic" Strategy

- Genitourinary
  - BPH
  - Electrolyte Depleters
  - Urinary Antispasmotics
- Infectious Disease
  - Cephalosporins
  - Macrolides
  - Quinolones
  - Antifungals
  - Anti-virals – Herpes
- Ophthalmic
  - Antibiotics
  - Antihistamines
  - Miotics
  - NSAIDs
- Otic
  - Antibiotics

Potential Drug Classes for "Step Through Generic" Strategy

- Respiratory
  - Antihistamines
  - Beta-Agonists
  - COPD
  - Leukotriene Modifiers
  - Nasal
- Topical
  - Acne
  - Antifungals
  - Corticosteroids
  - Parasitics

Preliminary Reaction

- Idea was announced in supplemental rebate email from ACS
- Medicaid staff have discussed with manufacturers
  - In previous years, manufacturers have expressed a willingness to give rebates while allowing a step through generic
  - Recent discussions have been favorable

Proposed New and Renamed Drug Classes

- New Classes
  - Cardiovascular
    - Antiarrhythmic Agents
    - Pulmonary Arterial Hypertension
  - Central Nervous System
    - Restless Legs Syndrome
  - Topical
    - Corticosteroids
- Renamed Classes
  - Analgesics
    - Gastroprotective NSAIDs
  - Blood Agents
    - Oral Anticoagulants
  - CNS (previously topical)
    - Neuropathic Pain

Reauthorization for Growth Hormone

- Initial authorization given based on diagnosis
  - Authorization length for AIDS wasting is 2-12 weeks depending on previous therapy and weight gain
  - Authorization length for all other diagnoses is 1 year
- No formal reauthorization criteria for diagnoses other than AIDS wasting

Reauthorization for Growth Hormone

- Proposal for Adults
  - Improvement in body composition:
    - Lean body mass
    - Total body water
    - Lean/fat ratio
    - Total body fat mass
    - Waist circumference
- Proposal for Children
  - Height gains
  - Epiphyses not closed
  - Patient not past puberty

DRAFT

Analgesic Agents: Gastroprotective NSAIDs

LENGTH OF AUTHORIZATIONS: 1 year, except as specified in items (2) and (3) under Additional Information

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to non-gastroprotective NSAIDs
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval. Acceptable contraindications include:
  - Concurrent or history of a GI event (perforation, ulcer, bleed)
  - Other risks for treatment with non-selective NSAIDs:
    - Coagulation disorders (i.e. hemophilia, chronic liver disease), erosive esophagitis
    - Documented NSAID-induced ulcer
    - Peptic ulcer disease (PUD)
    - Patient on anticoagulants (warfarin or heparin)
    - Patient on oral corticosteroids
    - Patient on methotrexate
- History of unacceptable/toxic side effects to medications not requiring prior approval including non-gastroprotective NSAIDs

ADDITIONAL INFORMATION

1. Preferred gastroprotective NSAIDs may be approved if there have been therapeutic failures to no less than a one-month trial of at least two non-gastroprotective NSAID medications.
2. Preferred gastroprotective NSAIDs may be approved for patients who are undergoing surgical or other medical procedures that may predispose them to potential bleeding complications. Authorization will be for a 2-month period.
3. Preferred gastroprotective NSAIDs may be approved for patients who are being treated for H. pylori. Authorization will be for a 30-day period.

CRITERIA FOR SYSTEMATIC PA OF PREFERRED AGENTS

1. Patient age equal to or over 60 years; or
2. Patient has claims history of warfarin, heparin, or heparin-related agents in past 120 days; or
3. Patient has claims history of oral corticosteroid in past 120 days; or
4. Patient has claims history of methotrexate in past 120 days; or
5. Patient has claims history of aspirin in past 120 days; or
6. If there have been therapeutic failures to no less than a one-month trial of at least two non-gastroprotective NSAID medications.

AGENTS UNDER REVIEW:

Arthrotec® (diclofenac/misoprostol)
Celebrex® (celecoxib)
Duexis® (famotidine/ibuprofen)
Vimovo® (esomeprazole/naproxen)

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Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATIONS: 1 year

INDICATIONS:

		Clopidogrel	Dabigatran	Prasugrel	Rivaroxaban	Ticagrelor	Warfarin
	Prophylaxis of DVT in patients undergoing total hip or knee replacement				✓		
Reduction of atherosclerotic events:	After cardiac valve replacement						✓
	In established peripheral arterial disease	✓					
	In non-STEMI ACS	✓		✓		✓	✓
	In non-valvular atrial fibrillation		✓		✓		✓
	In recent MI or stroke	✓					✓
	In STEMI ACS	✓		✓		✓	✓
	Venous thrombosis, pulmonary embolism						✓

DVT: deep vein thrombosis; STEMI: ST-elevated myocardial infarction; ACS: acute coronary syndrome; MI: myocardial infarction

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed therapeutic trials of <u>two weeks</u> with medications not requiring prior approval? If so, document and approve the requested medication.

AGENTS UNDER REVIEW:

Brilinta® (ticagrelor)
Effient® (prasugrel)
Plavix® (clopidogrel)
Pradaxa® (dabigatran)
warfarin (generic for Coumadin®)
Xarelto® (rivaroxaban)

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Cardiovascular Agents: Antiarrhythmics

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
3. Has the patient failed therapeutic trials of [to be discussed by P&T Committee] with [number of medications to be discussed by P&T Committee] not requiring prior approval? If so, document and approve the requested medication.

AGENTS UNDER REVIEW:

amiodarone (generic of Cordarone®)
disopyramide phosphate IR/ER (generic of Norpace®, Norpace CR®)
flecainide (generic of Tambocor®)
mexilitine
Multaq® (dronedarone)
propafenone IR/ER (generic of Rythmol®, Rythmol SR®)
quinidine gluconate ER
quinidine sulfate IR/ER
Tikosyn® (dofetilide)

DRAFT

Cardiovascular Agents: Pulmonary Arterial Hypertension

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed therapeutic trials of [to be discussed by P&T Committee] with [number of medications to be discussed by P&T Committee] not requiring prior approval? If so, document and approve the requested medication.

AGENTS UNDER REVIEW:

Inhalation
- Tyvaso® (treprostinil)
- Ventavis® (iloprost)

Intravenous
- epoprostenol (generic of Flolan®)
- Remodulin® (treprostinil)
- Veletri® (epoprostenol)

Oral
- Adcirca® (tadalafil)
- Letairis® (ambrisentan)
- Revatio® (sildenafil)
- Tracleer® (bosentan)

DRAFT

Central Nervous System (CNS) Agents: Neuropathic Pain

LENGTH OF AUTHORIZATIONS: [to be discussed by P&T Committee]

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial of at least two oral medications used for neuropathic pain.

AGENTS UNDER REVIEW:

amitriptyline (generic of Elavil®)
amoxapine
carbamazepine (generic of Tegretol®)
clomipramine (generic of Anafranil®)
Cymbalta® (duloxetine)
desipramine (generic of Norpramin®)
doxepin (generic of Sinequan®)
gabapentin (generic of Neurontin®)
Gralise® (gabapentin)
imipramine (generic of Tofranil®)
Lidoderm® (lidocaine Topical Patch)
Lyrica® (pregabalin)
nortriptyline (generic of Pamelor®)
oxcarbazepine (generic of Trileptal®)
protriptyline (generic of Vivactil®)
trimipramine (generic of Surmontil®)

DRAFT

Central Nervous System (CNS) Agents: Restless Legs Syndrome

LENGTH OF AUTHORIZATIONS: 1 year

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial of at least one medication not requiring prior approval

AGENTS UNDER REVIEW:

Horizant® (gabapentin enacarbil)
pramipexole IR (generic of Mirapex®)
ropinirole IR (generic of Requip®)

DRAFT

Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS: Duration of the prescription [maximum length to be discussed by P&T Committee]

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to at least two medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Has the patient failed therapeutic trials of two weeks with two medications not requiring prior approval?

Additional topics for P&T Committee discussion:
- Trials within potency category?
- Length of authorization dependent on potency category?

AGENTS UNDER REVIEW:

Low Potency
- alclometasone cream/ointment (generic of Aclovate®)
- betamethasone valerate cream/lotion (generic of Valisone®)
- Capex® shampoo (fluocinolone Acetonide)
- Desonate® gel (desonide)
- desonide cream/lotion/ointment (generic of Desowen®)
- desoximetasone 0.05% cream (generic of Topicort LP®)
- fluocinolone acetonide 0.01% cream/solution (generic of Synalar®)
- fluocinolone body/scalp oil (generic of Derma-Smoothe/ FS®)
- hydrocortisone acetate gel
- hydrocortisone cream/lotion/ointment/solution
- Pandel® cream (hydrocortisone probutate)
- Topicort® 0.05% ointment (desoximetasone)

Medium Potency
- betamethasone dipropionate lotion (generic of Diprolene®)
- Cloderm® (clocortolone pivalate)
- Cordran® tape (flurandrenolide)
- desoximetasone 0.25% cream, ointment, 0.05% gel (generic of Topicort®)
- fluocinolone acetonide 0.025% cream/ointment (generic of Synalar®)
- fluticasone propionate cream, lotion, ointment (generic of Cutivate®)
- hydrocortisone butyrate cream/ointment (generic of Locoid®)
- hydrocortisone valerate cream/ointment (generic of Westcort®)
- mometasone furoate cream/lotion/ointment (generic of Elocon®)
- prednicarbate cream/ointment (generic of Dermatop®)
- triamcinolone acetonide 0.025% cream/lotion/ointment (generic of Aristocort®, Kenalog®)

High Potency
- amcinonide ointment/cream/lotion
- Apexicon-E® (diflorasone diacetate emollient base) cream
- betamethasone dipropionate cream/ointment (generic of Diprolene®)
- betamethasone valerate ointment (generic of Valisone®)
- diflorasone diacetate cream (generic of Florone®)
- fluocinonide cream/gel/ointment/solution (generic of Lidex®)
- fluocinonide emulsified base cream (generic of Lidex-E®)
- Halog® cream, ointment (halcinonide)
- Kenalog® aerosol spray (triamcinolone acetonide)
- Luxiq® (betamethasone valerate foam)
- triamcinolone acetonide 0.1% lotion (generic of Kenalog®)
- triamcinolone acetonide 0.5% cream/ointment (generic of Aristocort®, Kenalog®)
- Vanos® cream (fluocinonide)

Very High Potency
- betamethasone dipropionate augmented cream/ointment/lotion/gel (generic of Diprolene AF®)
- clobetasol propionate cream/foam/gel/lotion/ointment/shampoo (generic of Olux®, Temovate®)
- clobetasol propionate emollient base cream (generic of Temovate-E®)
- Clobex® lotion/shampoo/spray (clobetasol propionate)
- diflorasone diacetate ointment (generic of Florone®)
- halobetasol propionate cream/ointment (generic of Ultravate®)
- Olux-E® foam (clobetasol propionate)