

Secretary for Health and Family Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Secretary for Health and Family Services based on the April 16, 2009 Pharmacy and Therapeutics Advisory Committee (PTAC) Meetings.

Description of Recommendation	P & T Vote	Final Decisions (s)
<p><u>Impact Analysis on Branded Products with Generic Components:</u> The following branded products with generic components should now require prior authorization:</p> <ul style="list-style-type: none"> • Dolgic® Plus • Fexmid® • Naprelan® • Xodol® • Ibudone® • Dexpak® 	<p>Passed 9 For 0 Against</p>	<p>The following branded products with generic components will now require prior authorization:</p> <ul style="list-style-type: none"> • Dolgic® Plus • Fexmid® • Naprelan® • Xodol® • Ibudone® • Dexpak®
<p><u>New Drugs to Market: Kapidex™</u> Place this product non preferred with appropriate quantity limits in the PDL category titled Proton Pump Inhibitors.</p>	<p>Passed 8 For 1 Against</p>	<p>Kapidex™ will be non preferred with appropriate quantity limits in the PDL category titled Proton Pump Inhibitors.</p>
<p><u>New Drugs to Market: Mozobil™</u> Since plerixafor will not be included on the KY PDL, allow this product to pay once the following criteria have been met:</p> <p>Plerixafor (Mozobil) will be approved via an ICD9 Override for:</p> <ul style="list-style-type: none"> • Diagnosis of autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) OR multiple myeloma (MM) 	<p>Passed 9 For 0 Against</p>	<p>Since plerixafor will not be included on the KY PDL, this product will pay once the following criteria have been met:</p> <p>Plerixafor (Mozobil) will be approved via an ICD9 Override for:</p> <ul style="list-style-type: none"> • Diagnosis of autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) OR multiple myeloma (MM)

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<p><u>New Drugs to Market: Uloric®</u> Until this class can be reviewed for inclusion on the KY PDL, allow febuxostat to pay once the following criteria have been met:</p> <p>Febuxostat (Uloric) will be approved if both of the following are true:</p> <ul style="list-style-type: none"> • Diagnosis of hyperuricemia associated with gout AND • Adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6 mg/dL OR intolerance or contraindication to allopurinol. 	<p>Passed 9 For 0 Against</p>	<p>Until this class can be reviewed for inclusion on the KY PDL, febuxostat will pay once the following criteria have been met:</p> <p>Febuxostat (Uloric) will be approved if both of the following are true:</p> <ul style="list-style-type: none"> • Diagnosis of hyperuricemia associated with gout AND • Adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6 mg/dL OR intolerance or contraindication to allopurinol.
<p><u>New Drugs to Market: Toviaz™</u> Place this product non preferred with appropriate quantity limits in the PDL category titled Urinary Tract Antispasmodics.</p>	<p>Passed 8 For 1 Against</p>	<p>Toviaz™ will be non preferred with appropriate quantity limits in the PDL category titled Urinary Tract Antispasmodics.</p>
<p><u>New Drugs to Market: Rapaflo™</u> Place this product non preferred in the PDL category titled Alpha Blockers for BPH.</p>	<p>Passed 8 For 1 Against</p>	<p>Rapaflo™ will be non preferred in the PDL category titled Alpha Blockers for BPH.</p>
<p><u>New Drugs to Market: Vectical™</u> Place this product non preferred in the PDL category titled Topical Agents for Psoriasis.</p>	<p>Passed 8 For 1 Against</p>	<p>Vectical™ will be non preferred in the PDL category titled Topical Agents for Psoriasis.</p>
<p><u>New Drugs to Market: Centany™</u> Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents.</p>	<p>Passed 8 For 1 Against</p>	<p>Centany™ will be non preferred in the PDL category titled Dermatologics: Antibiotic Agents.</p>
<p><u>New Drugs to Market: Vimpat®</u> Place this product non preferred in the PDL category titled Anticonvulsants: Second Generation; however, allow an electronic approval if patient has had an anticonvulsant claim in the past 90 days.</p>	<p>Passed 5 For 1 Abstention 3 Against</p>	<p>Vimpat® will be non preferred in the PDL category titled Anticonvulsants: Second Generation; however, claims will pay at point-of-sale if there is an anticonvulsant claim in the past 90 days.</p>

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<p><u>Immunosuppressants</u></p> <ol style="list-style-type: none"> 1. DMS to select all unique chemical entities as preferred on the PDL. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Immunosuppressant class, require a PA until reviewed by the PTAC. 	<p>Passed 9 For 0 Against</p>	<p><u>Selected Preferred Agent (s)</u> azathioprine cyclosporine mycophenolate mofetil Gengraf® Myfortic® Prograf® Rapamune®</p>
<p><u>Sedative Hypnotics</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one benzodiazepine with a quick onset, one with a long duration and one with an intermediate duration, chloral hydrate and generic immediate release zolpidem must be preferred. 2. Place quantity limits on agents in the category according to the FDA recommended maximum dose. 3. For patients greater than 65 years old, eszopiclone, ramelteon, zaleplon, zolpidem, or zolpidem ER will automatically pay without PA 4. For patients less than 65 years old, any non preferred agent should pay after trial and failure of 2 preferred agents within the past 90 days. 5. If ramelteon is not selected as preferred, it will be approved for patients with history of drug/alcohol dependence. 6. Agents not selected as preferred will require PA. 7. For any new chemical entity in the sedative hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 8 For 1 Abstention 0 Against</p>	<p><u>Selected Preferred Agent (s)</u> chloral hydrate estazolam^{QL} flurazepam^{QL} temazepam^{QL} triazolam^{QL} zolpidem^{QL}</p>

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<p><u>Sedative Hypnotic Clinical Criteria</u></p> <ol style="list-style-type: none"> 1. For patients greater than 65 years old, eszopiclone, ramelteon, zaleplon, zolpidem, or zolpidem ER will automatically pay without PA. 2. For patients less than 65 years old, any non preferred agent will automatically pay without PA after trial and failure of 2 preferred agents within the past 90 days. 3. For patients less than 65 years old and no claims history of sedative hypnotic use, non preferred products will be approved if: <ul style="list-style-type: none"> • There's a reason the patient cannot be changed to a medication within the same class not requiring prior approval (preferred medication). Acceptable reasons include: <ul style="list-style-type: none"> • Allergy to medications not requiring prior approval • Contraindication to or drug-to-drug interaction with medications not requiring prior approval • History of unacceptable/toxic side effects to medications not requiring prior approval • The requested non – preferred medication may be approved if both of the following are true: <ul style="list-style-type: none"> • If there has been a therapeutic failure on <u>two</u> preferred medications • The requested medication's corresponding generic (<u>if covered by the state</u>) has been attempted and failed or is contraindicated <p>SPECIAL CRITERIA FOR ROZEREM® (ramelteon) Rozerem® will automatically be approved for patients with a history of drug/alcohol abuse.</p>	<p>Passed 8 For 1 Abstention 0 Against</p>	<ol style="list-style-type: none"> 1. For patients greater than 65 years old, eszopiclone, ramelteon, zaleplon, zolpidem, or zolpidem ER will automatically pay without PA. 2. For patients less than 65 years old, any non preferred agent will automatically pay without PA after trial and failure of 2 preferred agents within the past 90 days. 3. For patients less than 65 years old and no claims history of sedative hypnotic use, non preferred products will be approved if: <ul style="list-style-type: none"> • There's a reason the patient cannot be changed to a medication within the same class not requiring prior approval (preferred medication). Acceptable reasons include: <ul style="list-style-type: none"> • Allergy to medications not requiring prior approval • Contraindication to or drug-to-drug interaction with medications not requiring prior approval • History of unacceptable/toxic side effects to medications not requiring prior approval • The requested non – preferred medication may be approved if both of the following are true: <ul style="list-style-type: none"> • If there has been a therapeutic failure on <u>two</u> preferred medications • The requested medication's corresponding generic (<u>if covered by the state</u>) has been attempted and failed or is contraindicated <p>SPECIAL CRITERIA FOR ROZEREM® (ramelteon) Rozerem® will automatically be approved for patients with a history of drug/alcohol abuse.</p>

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<p><u>Topical Antifungals</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, there should be agents representing multiple mechanisms of action as well as a combination product preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis. 4. For any new chemical entity in the Topical Antifungal class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 9 For 0 Against</p>	<p><u>Selected Preferred Agent (s)</u> clotrimazole nystatin cream nystatin ointment nystatin-triamcinolone</p>
<p><u>Vusion[®] Clinical Criteria</u> Approval will be granted for individuals meeting all of the following criteria:</p> <ul style="list-style-type: none"> • Recipient must have a diagnosis of diaper dermatitis; AND • Failed at least one conventional OTC or Rx therapy (zinc oxide, topical antifungal, hydrocortisone, A&D Ointment) for diaper dermatitis. 	<p>Passed 8 For 1 Abstention 0 Against</p>	<p>Approval will be granted for individuals meeting all of the following criteria:</p> <ul style="list-style-type: none"> • Recipient must have a diagnosis of diaper dermatitis; AND • Failed at least one conventional OTC or Rx therapy (zinc oxide, topical antifungal, hydrocortisone, A&D Ointment) for diaper dermatitis.
<p><u>Growth Hormone</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form. 2. Continue to require clinical PA for all agents, preferred or non-preferred. 3. Allow continuation of therapy for agents selected as non-preferred for patients who have a history within the last 90 days. 4. For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee. 	<p>Passed 9 For 0 Against</p>	<p><u>Selected Preferred Agent (s)</u> Genotropin^{® CC} Norditropin^{® CC} Saizen^{® CC}</p>

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<p><u>Growth Hormone Clinical Criteria</u> Approvable diagnosis via ICD9 Override:</p> <ol style="list-style-type: none"> 1. Growth Hormone Deficiency or Pituitary dwarfism 2. Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders, Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin, Other disorders of the pituitary gland and craniopharyngeal duct 3. Turner's Syndrome 4. Chronic renal insufficiency & end-stage renal disease (pre transplant) 5. Prader-Willi Syndrome 6. Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature 7. Small for gestational age 8. Short Stature Homeobox Gene 9. Noonan Syndrome 10. HIV wasting or cachexia 11. Short bowel syndrome <p>CRITERIA FOR APPROVAL OF A NON-PREFERRED GROWTH HORMONE: Patient needs to:</p> <ol style="list-style-type: none"> 1. Have ONE approvable diagnosis AND 2. Have a therapeutic failure to at least TWO preferred medications 	<p>Passed 9 For 0 Against</p>	<p>Approvable diagnosis via ICD9 Override:</p> <ol style="list-style-type: none"> 1. Growth Hormone Deficiency or Pituitary dwarfism 2. Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders, Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin, Other disorders of the pituitary gland and craniopharyngeal duct 3. Turner's Syndrome 4. Chronic renal insufficiency & end-stage renal disease (pre transplant) 5. Prader-Willi Syndrome 6. Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature 7. Small for gestational age 8. Short Stature Homeobox Gene 9. Noonan Syndrome 10. HIV wasting or cachexia 11. Short bowel syndrome <p>CRITERIA FOR APPROVAL OF A NON-PREFERRED GROWTH HORMONE: Patient needs to:</p> <ol style="list-style-type: none"> 1. Have ONE approvable diagnosis AND 2. Have a therapeutic failure to at least TWO preferred medications