

Script Notes



The Pharmacy and Therapeutics Newsletter for Keystone Mercy Health Plan Participating Providers

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Formulary Information & Resources

Ensuring providers have access to information regarding the formulary status of a medication, claims processing tips, and the opportunity to be involved in formulary additions and changes all play a key role in providing high quality patient care. Keystone Mercy Health Plan has several resources available for providers that allow them to easily access information regarding the formulary status of a medication, any limits imposed on a medication, and/or the prior authorization requirement/process. The following are some helpful formulary information resources and claims processing tips:

Formulary Information Resources:

Keystone Mercy has released a new online searchable formulary tool. This web-based formulary provides a comprehensive single source reference for formulary information. You may search alphabetically, by drug name, or by therapeutic class. Choosing a drug reveals icons representing formulary status, coverage restrictions, and prescriber notes. The site also allows for side-by-side comparison of formulary information for products in the same therapeutic category, making it easier for you to make informed decisions. Utilizing this tool is an excellent way to ensure you are prescribing the most cost-effective therapy. In addition, current and prospective members are able to determine if their medications are covered, identify restrictions, and view potential cost-effective alternatives.

To access the formulary tool click the “Searchable Formulary” link on the pharmacy page of our website: www.keystonemercy.com/pharmacy. You can search for a medication by clicking the appropriate first letter, typing the medication into the search box, or using the Therapeutic Class Search. Below are sample search results.

Drug Search: Ventolin HFA 90 mcg/Actuation Aerosol Inhaler:
1 drug(s) found

To view all covered medications in a therapeutic class, click any class hyperlink in your search results.

Brand Name <small>Generic Name</small>	Therapeutic Class <small>Sub-class</small>	Dose/Strength	Status	Notes & Restrictions
Ventolin HFA 90 mcg/Actuation Aerosol Inhaler	Beta-Adrenergic Agonists <u>Selective Beta-2-Adrenergic Agonists</u>	HFA Aerosol Inhaler - 90 mcg/Actuation	T1 Tier 1	QL Quantity Limit

1. Click the therapeutic class to view other available options in this class from the formulary.
2. Click the appropriate button for additional information on Quantity Limits and/or Age Limits.

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We welcome your thoughts, comments and/or suggestions. Do you have an idea for a story? Is there information we can provide to help you?

All correspondence concerning *Script Notes* should be sent to:

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Formulary Website Access

Access the Keystone Mercy Website 24 hours/7 days a week at www.keystonemercy.com/provider/formulary/index.asp
The formulary is updated on a quarterly basis.
We recommend saving it to your computer desktop for easy access.

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Epocrates® is another web-based quick reference tool available to determine the formulary status of medications. Epocrates is a dynamic clinical reference that provides up-to-date formulary information via palm pilot, PDA, or any internet connected computer or device. This tool enables you to access formulary status, view alternative and generic substitutions, and check for any limitations. For more information about Epocrates and instructions on how to register visit the website at www.epocrates.com.

Claims Processing Tips:

When a medication claim does not process at the pharmacy level it does not mean that the claim will never be paid. To have a claim process at the pharmacy level, there are different steps that can be taken, depending on the type of medication and the type of rejection that occurred. For instance, certain medications require prior authorization and will always reject at the pharmacy level without it. These medications include high-cost injectable medications (i.e., injectable chemotherapy agents, or biological agents), high cost specialty agents (i.e., oral chemotherapy agents or orphan drugs), and non-formulary medications. To get authorization for these agents, a prior authorization form must be completed and contain all of the required medical/patient information needed to determine the medical necessity of the request. To expedite the prior authorization process, it is important to completely fill out the proper prior authorization form. Prior authorization forms can be obtained by calling the Pharmacy Services Department at 1-800-588-6767 or going to the website www.keystonemercy.com/pharmacy/index.aspx.

There are, however, situations where a formulary medication will still reject at the pharmacy level. One example is when a formulary medication requires documentation of a trial with prerequisite medications. Without this documentation in a patient's medication history, the claim will reject at the pharmacy level and will require that a prior authorization form be completed and reviewed for medical necessity. Other reasons for a formulary medication not processing at the pharmacy level include:

- The request is being made for a dose that is outside of the FDA approved dosing range,
- Duplication of therapy with a previously paid claim,
- Or the request that is made for a brand name product when there is an AB-rated generic equivalent available.

For these claims to process the pharmacy may need to call the Call Center to discuss the situation and/or the provider may need to complete and submit a prior authorization form. Providers have the right to speak with a clinical pharmacist upon request to discuss a member's prescription that will not adjudicate.

Here is some additional information:

1. Requests for additions to the formulary or a change in prior authorization criteria
 - To request an addition to the formulary or change in prior authorization criteria contact the Pharmacy Services Department and a request form will be faxed or mailed to you.
2. Prior authorization forms for Specialty/Injectable medications
 - To obtain the prior authorization form needed for specialty and/or injectable medications you can either contact the Call Center or, for faster service, access the forms on our website at www.keystonemercy.com/pharmacy/index.aspx.
 - Prior authorization request numbers
 - Keystone Mercy phone: 1-800-588-6767
 - Keystone Mercy fax: 1-888-981-5202
3. Temporary supply information
 - If a patient's medication claim does not process at the pharmacy level because it requires prior authorization, the patient may still be able to obtain a small amount of the medication. Certain medications are eligible for up to a 5-day temporary supply. To obtain this temporary supply of medication for a patient, the pharmacy should use the authorization code supplied to them in the denial messaging or contact the Pharmacy Services department.
4. Days supply dispensing limitations
 - Maximum days supply is 34 days.

Refill frequency

- Members may have their prescriptions refilled when 85% or more of the medications is utilized.

Keystone Mercy Health Plan is committed to providing access to formulary information and claims processing tools to assist providers in delivering high quality care for our members. If you have any questions not addressed in this article, please contact the Keystone Mercy Pharmacy Services Department at 1-800-588-6767.

References

1. Medimedia Information Technologies. Available at: <http://www.mminfotech.com/news-s.asp?pid=7>. Accessed January 2009.
2. Epocrates PDA Medical Software. Available at: <http://www.epocrates.com>. Accessed January 2009.

Formulary Update: Additions to the Keystone Mercy Drug Formulary

Drug	Indication	Starting Dose	Strength on Formulary
Abilify® (aripiprazole)	Schizophrenia in patients >13 years Bipolar I disorder in patients > 10 years Adjunctive treatment of major depressive disorder (MDD) in adults	Schizophrenia (adults): 10-15 mg/day Schizophrenia (adolescents): 2 mg/day Bipolar Mania (adults): 15 mg/day Bipolar Mania (pediatrics): 2 mg/day MDD: 2-5 mg/day	Discmelt: 10 mg and 15 mg Solution: 1 mg/ml
Aldara® (imiquimod)	Actinic keratosis Superficial basal cell carcinoma External genital warts	Actinic keratosis: Apply 2 times/week for 16 weeks Superficial basal cell carcinoma: Apply 5 times/week for 6 weeks External genital warts: Apply 3 times/week for maximum of 16 weeks	Cream: 5%- 24 packet
Emla® (lidocaine/prilocaine)	Topical anesthetic for normal intact skin for local analgesia Topical anesthetic for genital mucous membrane for superficial minor surgery	Apply thick layer and cover with occlusive dressing (Refer to package insert for specific dosing administration)	Cream: 5/gm and 30/gm
Exelon® (rivastigmine tartrate)	Treatment of mild-moderate dementia of: -Alzheimer's disease -Parkinson's disease	Dementia of Alzheimer's type: 1.5 mg twice daily; maintenance dose: 3-6 mg twice daily Dementia of Parkinson's disease: 1.5/mg twice daily; maintenance dose: 1.5-6/mg twice daily	Patches: 4.6 mg/24 hr and 9.5 mg/24 hr
Pravachol® (pravastatin)	Hyperlipidemia Primary prevention of coronary events Secondary prevention of cardiovascular events	Greater than 14 yrs old: 40 mg once daily 8-13 yrs old: 20 mg once daily	Tablet: 80/mg
Simcor® (niacin/simvastatin)	Hypercholesterolemia	500 mg once daily at bedtime then titrate to patient response	Tablet: 20/500/mg, 20/750/mg, and 20/1000/mg
Sonata® (zaleplon)	Short-term treatment of insomnia	5-10 mg once daily at bedtime	Capsule: 5/mg and 10/mg
Venlafaxine Extended Release	Major Depressive Disorder (MDD) Social Anxiety Disorder (SAD)	MDD: 75 mg once daily; max dose 225mg/day SAD: 75 mg once daily	Tab OSM: 37.5/mg, 75/mg, 150/mg, and 225/mg
Zofran® (Ondansetron)	Prevention of nausea and vomiting associated with -moderate-high emetogenic chemotherapy -radiotherapy in patients Prevention of postoperative nausea and/or vomiting	High emetogenic: three 8 mg tablets 30 minutes prior to chemotherapy Moderate emetogenic: one 8 mg tablet twice daily Radiotherapy: one 8 mg tablet three times a day Postoperative: two 8 mg tablets 1 hr prior to induction of anesthesia	Tablet: 4/mg and 8/mg ODT: 4/mg and 8/mg Solution: 4/mg/5 ml For quantities not exceeding 15 tabs/ 30 days or 50 mls/ 30 days.

References

1. Abilify® Prescribing Information. Bristol-Myers Squibb. November 2008.
2. Aldara® Prescribing Information. Graceway Pharmaceuticals LLC. November 2007.
3. Emla® Prescribing Information. AstraZeneca. May 2005.
4. Exelon® Prescribing Information. Novartis. June 2006.
5. Pravachol® Prescribing Information. Bristol-Myers Squibb. March 2007.
6. Simcor® Prescribing Information. Abbott. August 2008.
7. Sonata® Prescribing Information. Wyeth Pharmaceuticals Inc. November 2007.
8. Venlafaxine Extended Release Prescribing Information. Osmotica Pharmaceutical. January 2009.
9. Zofran® Prescribing Information. GlaxoSmithKline. February 2006.

Product Updates:

Trilipix™ (fenofibric acid) is a fenofibric acid derivative. It is indicated for the adjunctive treatment of mixed dyslipidemia in patients with coronary heart disease (CHD) or a CHD risk equivalent when used in combination with statin therapy and diet to reduce triglyceride and increase HDL-C levels, adjunctive treatment to diet for severe hypertriglyceridemia to reduce triglyceride (TG) levels, adjunctive treatment to diet for primary hyperlipidemia and mixed dyslipidemia to reduce lipoprotein cholesterol (LDL-C), total cholesterol, TG, and apolipoprotein B. The recommended dose is 135 mg when used in combination with statin therapy, primary hyperlipidemia and mixed dyslipidemia. The recommended initial treatment dose for severe hypertriglyceridemia is 45 to 135 mg daily, which may be titrated to a maximum of 135 mg daily. Trilipix can be taken with or without food. The use of Trilipix is contraindicated in patients with severe renal impairment, patients with liver impairment, patients with preexisting gallbladder disease, nursing mothers and patients with a known hypersensitivity to fenofibric acid, choline fenofibrate or fenofibrate. Patients with mild to moderate renal impairment (CrCl between 30-80 ml/min) should initially receive 45 mg once daily and the dosage should be increased only after the effects on both renal function and lipid levels have been demonstrated. The use of Trilipix in patients with hepatic impairment has not been evaluated. The most commonly reported adverse events (>10%) in clinical trials were constipation, diarrhea, dyspepsia, nausea, pain, nasopharyngitis, sinusitis, upper respiratory tract infection, arthralgia, back pain, myalgia, headache and dizziness. Trilipix is available in 45 and 135 mg delayed release capsules.

Apriso™ (mesalamine) is a 5-aminosalicylic acid derivative. It is indicated for the maintenance of remission of ulcerative colitis in patients ≥ 18 years of age. The recommended dose is 1.5 g (four 0.375g capsules) every morning with or without meals. Apriso should not be co-administered with antacids. Apriso is contraindicated in patients with a known hypersensitivity to salicylates or aminosalicylates. Caution should be exercised when administering Apriso to patients with a known history of renal dysfunction, history of renal disease, and patients with pre-existing liver disease. The most common side effects (≥ 3 %) seen in clinical trials were headaches, diarrhea, upper abdominal pain, nausea, nasopharyngitis, influenza-like syndrome, and sinusitis. Apriso is available as 0.375 g gelatin capsules.

Banzel™ (rufinamide) is an anti-epileptic drug which

is a triazole derivative. It is indicated as an adjunctive anti-epileptic therapy for patients ≥ 4 years of age with Lennox-Gastaut syndrome. The initial recommended pediatric dose for children ≥ 4 years is 10 mg/kg/day divided into two equally divided doses, which can be increased by 10 mg/kg increments every other day up to a target dose of 45 mg/kg/day or 3200 mg/day (whichever is less). The initial recommended treatment dose for adults is 400-800 mg daily which is divided into two equally divided doses, which can be increased by 400-800 mg daily every other day until a maximum daily dose of 3200 mg is achieved. Banzel should be taken with food. No dosing adjustment is necessary for patients with renal impairment; however those receiving hemodialysis may require supplemental doses following dialysis since approximately 30% can be removed. Banzel should be used cautiously in patients with mild to moderate hepatic impairment and is not recommended in patients with severe hepatic impairment. Banzel is contraindicated in patients with Familial Short QT syndrome. Banzel decreases the efficacy of oral contraceptives (please refer to the package insert for a complete list of drug-drug interactions). The most frequent adverse events seen in clinical studies (>10%) were QT shortening, headache, somnolence, dizziness, fatigue, nausea and vomiting. Antiepileptic drugs may increase suicidal ideation; therefore Banzel's package insert also warns of this potential risk and a medication guide must be provided upon dispensing. Banzel is available as 200 mg and 400 mg scored tablets.

Keppra XR™ (levetiracetam) is an extended release antiepileptic drug. It is indicated for use as an adjunctive therapy in the treatment of partial onset seizures in patients ≥ 16 years of age with epilepsy. The starting dose is typically 1000 mg by oral route once daily, which may then be adjusted in increments of 1000 mg every 2 weeks up to the maximum recommended dose of 3000 mg per day. Please refer to full prescribing information for any dose adjustments needed for patients with impaired renal function. No dose adjustment is necessary in patients with hepatic impairment. Keppra XR should not be used in patients with a known hypersensitivity to levetiracetam or any other component of the formulation. It should be noted that Keppra XR may result in neuropsychiatric adverse reactions (somnolence, dizziness, and behavioral abnormalities), withdrawal seizures (when not withdrawn gradually), and possible hematologic abnormalities (low neutrophil count) and LFT abnormalities. The most common side effects (≥5%) associated with Keppra XR includes somnolence and

Product Updates:

irritability. Please refer to the package insert for a complete list of drug-drug interactions. Due to the FDA's recent analysis of the increased risk of suicidal behavior/ideation with antiepileptic drugs, it has been determined that Keppra XR will be labeled with a warning concerning this risk, along with a medication guide to efficiently inform patients. Keppra XR is available in 500 mg tablets.

Sancuso® (Granisetron Transdermal System) is a serotonin subtype 3 (5-HT₃) receptor antagonist. It is indicated for the prophylaxis of nausea and vomiting in patients receiving moderate-to-high emetogenic chemotherapy for a maximum of 5 consecutive days. The safety and efficacy of Sancuso has not been established in pediatric patients. A single patch should be applied to the upper outer arm at least 24 hours prior to chemotherapy; however, a patch should not be worn greater than 48 hours before chemotherapy. The patch must be worn for at least 24 hours post chemotherapy and may be worn for up to 7 days depending on the chemotherapy regimen duration. Dose adjustments are not needed for renal or hepatic impairment. The patch should not be used in patients with a known hypersensitivity to the active ingredient granisetron or any other component of the formulation. Sancuso may result in application site reactions and may mask a progressive ileus and/or gastric distention resulting from the underlying condition. When applied to the skin, the patch needs to be protected from natural and artificial sunlight. The most common side effect associated with the patch is constipation. No clinically significant drug-drug interactions were reported. Sancuso is available as a 52 cm² patch containing 34.3 mg of granisetron, which delivers 3.1 mg every 24 hours.

References

1. Abbott Laboratories. Prescribing Information for Trilipix™. December 2008.
2. Salix Pharmaceuticals. Prescribing Information for Apriso™. October 2008.
3. Eisai Inc. Prescribing Information for Banzel™. November 2008.
4. UCB Pharma, Inc. Prescribing Information for Keppra XR™. September 2008.
5. ProStrakan, Inc. Prescribing Information for Sancuso®. August 2008.

Ventolin® HFA - Preferred Albuterol HFA Product

Due to the elimination of Chlorofluorocarbon (CFC) propelled inhalers as of December 31, 2008, Ventolin® HFA is our preferred albuterol inhaler.

Highlights:

- ✓ Non-preferred HFA Inhalers (Proventil® HFA and ProAir® HFA) will require prior authorization.
- ✓ There is pharmacy messaging in place for Proventil® HFA and ProAir® HFA stating, "Ventolin® HFA is the preferred drug."
- ✓ Upon receiving a new prescription or refill order for Proventil® HFA or ProAir® HFA, the pharmacy can contact the prescriber for approval to dispense Ventolin® HFA.

Safety Alerts:

Raptiva® - New Black Box Warning

The FDA has approved a Boxed Warning for Raptiva® (efalizumab) to warn patients and prescribers of the potential risk of life-threatening infections, including progressive multifocal leukoencephalopathy (PML). Post-marketing surveillance studies have prompted these labeling revisions and the FDA is also requiring a submission of a Risk Evaluation and Mitigation Strategy (REMS) that will include a medication guide for patients and a timetable assessment of the REMS. The new warning will also emphasize the risk of bacterial sepsis, viral meningitis, invasive fungal disease, progressive leukoencephalopathy and other opportunistic infections. Raptiva is a monoclonal antibody which treats psoriasis through suppression of the body's immune system; however this mechanism leads to unintended infections and malignancies. Patients receiving Raptiva therapy should be educated to recognize the signs and symptoms of serious infections and should notify their health care providers if evidence of these symptoms exists. Health care providers should closely monitor all patients treated with Raptiva for signs of infection. A review of the revised prescribing information can be found at: www.gene.com/gene/products/information/pdf/raptiva-prescribing.pdf.

New Safety Measures for Oral Sodium Phosphate Products

The FDA issued a new Boxed Warning for Visicol® and OsmoPrep® to warn patients and health care providers of the risk of acute phosphate nephropathy (an acute kidney injury). Over-the-counter (OTC) products, such as Fleet Phospho-soda, also pose the same hazard when used at high doses for bowel cleansing, and their product labeling will also be updated to reflect the potential risk of kidney injury. The onset of kidney injury can vary, occurring anytime from hours after use to up to 21 days after discontinuation of oral sodium phosphate products. The use of oral sodium phosphate products should be avoided in children less than 18 years of age or in combination with other laxative products that contain sodium phosphate. The FDA also advises that these medications should be used cautiously in the following patient populations:

- Patients over 55 years of age
- People who suffer from dehydration, kidney disease, acute colitis and/or delayed bowel emptying
- Patients taking medications that affect kidney function, such as diuretics, angiotension converting enzyme inhibitors, angiotension receptor blockers, and nonsteroidal anti-inflammatory medications.

Serious Skin Reactions with Phenytoin and Fosphenytoin

The FDA is evaluating preliminary data which shows a potential increased risk of serious skin reactions from phenytoin therapy in Asian patients who are positive for the human leukocyte antigen (HLA) allele, HLA-B*1502. The type of skin reactions includes Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). The risk is also applicable to fosphenytoin since it is the prodrug which is metabolized to phenytoin. An identical alert was also released in December 2007 regarding the use carbamazepine in HLA-B*1502 allele positive Asian patients. Therefore, if patients have this allele, they should not receive phenytoin or fosphenytoin as alternatives to carbamazepine use.

New Warnings for Antiepileptic Drugs

The FDA is now requiring the manufacturers of antiepileptic to medications update their product labeling to include a new warning stating that use of these medications may increase the risk of suicidal thoughts and behaviors. Manufacturers must also submit a Risk Evaluation and Mitigation Strategy and provide medication guides for patients. The medications affected by this warning include: carbamazepine, clonazepam, clorazepate, divalproex sodium, ethosuximide, ethotoin, felbamate, gabapentin, lamotrigine, lacosamide, levetiracetam, mephenytoin, methosuximide, oxcarbazepine, phenytoin, pregabalin, primidone, rufinamide, tiagabine, topiramate, trimethadione, valproic acid and zonisamide. Patients receiving these medications should be monitored closely for emergence of or worsening depression, suicidal thoughts/behavior, and changes in mood or behavior.

Topical Anesthetics- Public Health Advisory

The FDA has released a Public Health Advisory regarding the potential hazards of skin numbing products, such as topical anesthetics used for cosmetic procedures. Topical anesthetics contain medications such as lidocaine, tetracaine, benzocaine and prilocaine and may be available with or without a prescription. The application of topical anesthetics for an intended medical procedure is normally done by a trained health care professional; however this is not the standard protocol for cosmetic procedures. If large amounts of anesthetics are applied to the skin it may result in dangerously elevated serum levels and lead to severe side effects, such as irregular heartbeats, seizures and/or death. Prior to use of a topical anesthetic the FDA recommends considering the following:

Safety Alerts:

- Use an FDA-approved topical anesthetic. A list of FDA approved numbing agents, is available at: www.fda.gov/cder/drug/advisory/topical_anesthetics.htm.
 - Select a topical anesthetic with the lowest concentration of the active anesthetic possible to relieve the anticipated pain.
 - Review instructions with your patients on how to safely use the topical anesthetic.
 - Apply the smallest amount of the topical anesthetic to the skin for the shortest time period possible. If the skin will be wrapped or covered, this will increase the chance of side effects.
2. Information for Health Care Professionals: Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab) and Remicade® (infliximab). September 2008. Available at: http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm.
 3. FDA News: FDA Requires New Safety Measures for Oral Sodium Phosphate Products to Reduce Risk of Acute Kidney Injury. December 2008. Available at: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01923.html>.
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 5. Information for Health Care Professionals: Phenytoin (marketed as Dilantin®, Phenytek® and generics) and Fosphenytoin Sodium (marketed as Cerebyx® and generics). November 2008. Available at: http://www.fda.gov/cder/drug/InfoSheets/HCP/phenytoin_fosphenytoinHCP.htm.
 6. FDA News: FDA Requires Warnings about Risk of Suicidal Thoughts and Behavior for Antiepileptic Medications. December 2008. Available at: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01927.html>.
 7. FDA Public Health Advisory: Life-Threatening Side Effects with the Use of Skin Products Containing Numbing Ingredients for Cosmetic Procedures. January 2009. Available at: http://www.fda.gov/cder/drug/advisory/topical_anesthetics.htm.
 8. Early Communication about an Ongoing Safety Review of clopidogrel bisulfate (marketed as Plavix®). January 2009. Available at: http://www.fda.gov/cder/drug/early_comm/clopidogrel_bisulfate.htm.

Ongoing Safety Review of Plavix® (clopidogrel bisulfate)

The FDA is currently aware of case reports that show clopidogrel is less effective in certain patient populations. Clopidogrel is an antiplatelet drug which prevents the formation of blood clots that could cause heart attacks or strokes in at-risk patients. Several reports have proposed that concomitant use of clopidogrel and proton pump inhibitors (PPIs) will decrease the efficacy of clopidogrel through enzyme inhibition. No clinical evidence exists that shows a similar effect with other medications that reduce stomach acid, such as H2 blockers and antacids. The manufacturers of clopidogrel (Sanofi-Aventis and Bristol-Myers Squibb) have decided to conduct further studies to evaluate the effects of genetic factors and other medications on clopidogrel's efficacy. The current FDA recommendations include:

- Clopidogrel should be prescribed by health care providers and taken by patients as directed due to its beneficial effects in reducing the incidence of blood clots.
- Health care providers should evaluate the need for initiating PPI therapy or continuing PPI therapy in patients receiving clopidogrel.
- If a patient is receiving or considering taking a PPI, they should consult their health care provider.

References

1. FDA New: FDA Approves Updated Labeling for Psoriasis Drug Raptiva®. October 2008. Available at: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01905.html>.

Script Notes

We welcome your thoughts, comments and/or suggestions.

Do you have an idea for a story?

Is there information we can provide to help you?

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