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Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met May 15, 2012. 2 products were added in the *Formulary* and no drugs were deleted from the *Formulary*. 4 products were designated nonformulary and not available and 1 drug a high-priority nonformulary drug. 2 interchanges were approved and criteria for use changes were approved for 2 drugs. 1 drug was evaluated, but no change was made to its formulary status.

◆ ADDED

Clobazam (Onfi®)

Pancrelipase (Viokace®)

◆ DELETED

None

◆ NONFORMULARY AND NOT AVAILABLE

Alendronate Sodium Effervescent Tablets (Binosto®)*
**Patients may NOT use their own supply from home*

Exenatide Extended-Release Injection (Bydureon®)*

Pancrelipase (Ultresa®)†
†Patients MAY use their own supply or be changed to Zenpep®

Peginesatide (Omontys®)*

◆ HIGH-PRIORITY NONFORMULARY DRUGS

Mifepristone (Korlym®)‡
‡Patients must use their own supply (restricted distribution)

◆ INTERCHANGES

Fluticasone Nasal Spray (Generic) for **Beclomethasone Aerosol Nasal Spray** (Qnasl®)

Zenpep® for **Ultresa®**

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NEWS

Don't get burned: Use sunscreen appropriately

It is the time of year to protect our families, our patients, and ourselves from overexposure to the sun. The Florida sun is intense. Outdoor activities can be necessary or even fun, but without the appropriate sun protection, being outdoors in Florida can be dangerous.

Skin cancer is an increasing concern. Skin cancer is the most common type of cancer in the United States with over 3.5 million skin cancers diagnosed every year. It is also one of the most preventable types of cancer. The American Cancer Society estimates that one American dies every hour from skin cancer. You can take action to decrease these risks.

Skin cancer prevention includes avoiding tanning booths, avoiding sun exposure in the middle of the day (ie, between 10 AM and 2 PM), wearing protective clothing (shirts, hats, and sunglasses), and the appropriate use of a good sunscreen. Overexposure to the sun is a particular concern for children. Severe sunburns in childhood may increase the risk of melanoma later in life.

Photoaging also takes its toll. We all want to be skin-cancer free and avoid the sun's aging effects. Sunscreens can help.

Recently, the FDA has proposed new regulations that will help consumers use sunscreens appropriately. Sunscreens block some ultraviolet (UV) radiation from damaging your skin. UV type A radiation (UVA) causes cells to age and can damage DNA in skin cells. UVA radiation is most associated with photoaging (wrinkles and loss of skin elasticity), but it is also associated with skin cancer. UV type B radiation causes sunburn and is thought to be the major cause of skin cancers. Thus, avoiding sunburns is perceived as a way to minimize the risk of skin cancer. Avoiding sunburns does not mean you avoid the risks of skin cancer totally.

For years, we have been told to use a sunscreen with a sun protection factor (SPF) of at least 30. This SPF represents relative protection against UVB radiation with higher numbers being better. An SPF of 30 suggests that, when properly applied, the sunscreen will allow the user to be in the sun for an hour, yet only receive the equivalent of 2 minutes in the sun unprotected. Less UVB exposure results in fewer sunburns and the associated long term risks.

The Food and Drug Administration is now requiring sunscreen manufacturers to change their labels to be more consistent and meaningful for consumers. These new regulations should be fully implemented by December of this year. Why wait for the new labels? Use these impending labeling changes to use sunscreens properly.

When the term "broad spectrum" is used on sunscreens, they will have to protect against both UVB and UVA. Remember, SPF only referred to UVB protection. Look for a broad-spectrum product and verify on the label that it blocks both UVB and UVA. Higher SPF numbers are better for UVB protection, but do not be surprised if your favorite SPF-100 product goes away with the new labeling. FDA does not have data showing that an SPF greater than 50 provides any additional benefit.

Water-resistance claims are going to have to be explicit. How long will these products work while sweating or swimming? No sunscreen is sweatproof or waterproof. Tell your patients to reapply at least every 2 hours, even if the product is supposed to be water resistant. Consider reapplying a water-resistant sunscreen more frequently than every 2 hours for best protection, especially when you are in the water or are sweating.

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Formulary update, *from page 1*

◆ **CRITERIA-FOR-USE CHANGES**

Clopidogrel (Generic)¶
¶Alternative therapy recommended if activation is impaired

Vasopressin for Diabetes Insipidus in Children¶
¶One standard concentration (0.01 units/mL)

Clobazam is a benzodiazepine with anticonvulsive and anxiolytic properties. It has a labeled indication as an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older.

LGS is a severe form of childhood-onset epilepsy. Therapy is complicated by multiple seizure types and resistance of seizures to pharmacologic treatment. Benzodiazepines have been recommended as add-on therapy to other antiepileptics including valproic acid, lamotrigine, topiramate, rufinamide, and felbamate.

Clobazam's dosage should be based on weight and titrated weekly to the target dose (less than or equal to 30 kg up to 20 mg; greater than 30 kg up to 40 mg). For the elderly, poor CYP2C19 metabolizers, or patients with mild to moderate hepatic impairment, dosage should be adjusted. For patients with mild to moderate renal impairment, no dose adjustment is required. There is no experience with clobazam in severe renal impairment. Discontinuation of clobazam requires tapering by decreasing the dose every week by 5-10 mg/day to prevent withdrawal symptoms.

Efficacy of clobazam for LGS was evaluated in 2 randomized, controlled trials: one phase III trial and 1 phase II trial. Both studies support short-term efficacy of clobazam as an adjunctive therapy to other antiepileptics including valproic acid for drop seizures associated with LGS. Efficacy showed a dose-response relationship up to 40 mg/day. Clobazam's long-term efficacy for LGS is being evaluated in an open-label study, which enrolled 204 patients from a phase III trial and 61 patients from phase a II trial. As of July 1, 2010, 213 (79.8%) remained in the study receiving clobazam. Of these, 89% (189 patients) had received clobazam for greater than or equal to 1 year, and 44 of 61 patients from phase II remained in the study approximately 4 years after entry. No safety data are available to date from the open-label study.

Common adverse events include somnolence, pyrexia, lethargy, drooling, and constipation. Serious adverse events reported in greater than 2 patients during the phase III clinical trial were lobar pneumonia and pneumonia. There are no known contraindications to clobazam. Potential shortcomings of clobazam include tolerance, physical and psychological dependence, central nervous system depression, drug interactions, and possible confusion with clonazepam. The cost per day is over $20 for the maximum 40-mg/day dose. Thus, it is an expensive option; however, due to the rarity of LGS, use is expected to be low.

Considering the complexity and difficulty in controlling the seizures associated with LGS, clobazam is not expected to replace other currently available antiepileptic drugs. It will likely be used as second- or third-line adjunctive therapy and continuation of patients' home regimens.

Clobazam is a controlled substance and patients cannot use their own supply from home. Therefore, it was added in the *Formulary*.

Pancrelipase is a mixture of the pancreatic enzymes lipase, protease, and amylase. Although pancrelipase products had been on the market for decades, they were unapproved drugs. The FDA mandated that manufacturers of pancreatic enzyme replacement products seek approval through the NDA process in 2004. There were concerns about the lack of standardization and equivalency of these products. In Florida, pancrelipase is listed in the Negative Formulary and products cannot be interchanged in the community setting.

In June 2010, the P&T Committee added Creon®, Pancreaze®, and Zenpep® dosage forms in the *Formulary* and approved an interchange protocol while a patient is hospitalized based on keeping the amount of lipase in the dosage form within 20% of the pancrelipase product the patient had been receiving. As new pancrelipase products are approved, the interchange protocol will continue to be revised.

Ultresa® is a combination of porcine-derived lipases, proteases, and amylases in an enteric-coated dosage form with a labeled indication for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis (CF) or other conditions. This is the newly marketed version of what used to be formerly known as Ultrase®.

Patients with CF have a more viscous intestinal lumen, which causes luminal obstruction, fibrosis, and exocrine pancreatic insufficiency. Severe disease can lead to unabsorbed substrates reaching the colon and being excreted in the feces. Enzyme insufficiency can occur in the course of chronic pancreatitis and pancreatic carcinoma. Consequences of the loss of exocrine function are malabsorption, steatorrhea, weight loss, and malnutrition. Ultresa® ultimately replaces the enzymes that aid in digestion of fats, protein, and carbohydrates; thereby acting like digestive enzymes physiologically secreted by the pancreas.

The dosing of Ultresa® is based on the lipase component. Ultresa® is available in 3 delayed-release capsule strengths containing 13,800 units, 20,700 units, or 23,000 units of lipase. Children between 12 months and 4 years of age weighing greater than 14 kilograms should begin with a dose of 1,000 lipase units/kg/meal. Children older than 4 years of age weighing 28 kg should start with 500 lipase units/kg/meal to a maximum of 2,500 lipase units/kg/meal. Ultresa® is not approved for use in patients under these weight limits.

Ultresa® has shown benefit in improving digestion of macronutrients. In a randomized, crossover study, the mean coefficient of fat absorption (CFA) for the Ultresa® group was 89% compared to 56% in the placebo group. The mean difference was 35%. A subgroup analysis was performed that showed mean change in CFA was greater in patients with lower placebo CFA values than in patients with higher placebo CFA values. When the results were stratified by age and gender, similar responses were seen.

The coefficient of nitrogen absorption (CNA) was also determined during both treatment regimens. The mean CNA value for the Ultresa® arm was 84% compared to 59% in the placebo arm with a mean difference of 26%.

Ultresa® was designated nonformulary and not available and will be interchanged to an equivalent dose of Zenpep®. If patients would like to use their supply of Ultresa®, they may do so upon a physician's order.

Viokace® is a non-enteric-coated combination of porcine-derived lipases, proteases, and amylases, with a labeled indication in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy, in combination with a proton pump inhibitor. Viokace® is the only pancrelipase product with this labeled indication.

Chronic pancreatitis comprises a spectrum of disorders ranging from intermittent inflammatory flares, persistent pain, and end-stage exocrine failure. Enzyme insufficiency occurs late in the course of chronic pancreatitis. Treatment of pain associated with chronic pancreatitis is challenging. Abdominal pain has been suggested to be caused by inflammation, elevated duct pressure, and an abnormal negative feedback mechanism. Abdominal pain relief in chronic pancreatitis uses non-enteric coated enzyme preparations to

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Formulary update, *from page 2*

inhibit negative feedback of the pancreas. The supplementation of endogenous proteases inactivates CCK-releasing peptide, decreasing CCK release. This decreases pancreatic stimulation and may decrease pain. Because this occurs in the proximal small intestine, the delivery of endogenous proteases must be to the upper small intestine. This can be done consistently only with non-enteric coated pancreatic enzyme products.

The dosing of Viokace® is based on the lipase component. Enzyme dosing should begin with 500 lipase units/kg/meal to a maximum of 2,500 lipase units/kg/meal or less than 10,000 lipase units/kg/day.

Viokace®'s safety and efficacy were evaluated in 1 study with patients who had exocrine pancreatic insufficiency associated with chronic pancreatitis and pancreatectomy. In this randomized, placebo-controlled trial, the mean coefficient of fat absorption (CFA) was 86% with Viokace® treatment versus 58% with placebo. The mean difference was 28%. The CFA serves as a surrogate marker for appropriate digestion of meals and is determined by subtracting the excreted fat amount from the ingested amount of fat and dividing that difference by the amount of fat ingested.

Viokace® was added in the *Formulary* and will not be interchanged with formulary alternatives because it is a different formulation of pancrelipase (ie, non-enteric coated), which may have increased benefit over other formulations in patients with chronic pancreatitis.

Binosto® is an **effervescent tablet formulation of alendronate sodium** used for the treatment of osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis. It is a once-weekly effervescent tablet that rapidly dissolves in water to make a buffered solution.

Gastrointestinal ulceration is a possible adverse event associated with bisphosphonates. Administration precautions must be taken to avoid this, including taking the drug with 6 to 8 ounces of water and not lying down for at least 30 minutes and until after their first meal. Adherence to these precautions is difficult while patients are hospitalized. Because of this, alendronate was designated nonformulary and not available in June 1999. In April 2008, alendronate tablets were added in the *Formulary*, but restricted to pharmacist approval in patients hospitalized for greater than 7 days who can follow administration instructions sufficiently to avoid esophageal ulceration. Binosto® was designated nonformulary and not available.

Bydureon® is an **extended-release exenatide injection**. Exenatide is a glucagon-like peptide-1 (GLP-1) receptor agonist with a labeled indication as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes. Bydureon® is administered subcutaneously once weekly without regard to time of day or food consumption.

Exenatide was originally approved for the same indication as a regular-release formulation [Byetta®] to be administered twice daily as a subcutaneous injection within the 60-minute period before morning and evening meals. It was listed in the *Formulary* in March 2008.

Bydureon® contains a boxed warning concerning the risk of thyroid C-cell tumors. Extended-release exenatide caused C-cell tumors at clinically relevant exposures in rats. It is unknown whether this effect would be present in humans. Because of this, Bydureon® is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome, and is not recommended as first-line therapy for type-2 diabetes. A Risk Evaluation and Mitigation strategy is in place.

Bydureon® was designated nonformulary and not available. The regular-release injection could be used if exenatide therapy is needed during a hospitalization.

Peginesatide is an erythropoiesis-stimulating agent for the treatment of anemia in adult dialysis patients with chronic kidney disease (CKD). It is only indicated for use in patients on dialysis. It is not used for patients receiving chemotherapy where anemia is not due to CKD nor is it used as a substitute for blood transfusions in patients who need immediate anemia correction.

Peginesatide differs from erythropoietin and darbepoetin; it is a synthetic peptide-based erythropoietin-receptor agonist with an amino acid sequence unrelated to erythropoietin. It is also administered monthly rather than daily or weekly.

Peginesatide includes a REMS program warning of the increased risk of cardiovascular events in patients with CKD not on dialysis. Peginesatide was designated nonformulary and not available.

Mifepristone is a synthetic steroid with potent antiprogesterone and antiglucocorticoid activity. Mifepristone is most widely known as a postcoital contraceptive agent and, when used in combination with a prostaglandin, as an abortifacient in early pregnancy (RU-486). Because of its antiglucocorticoid activity, mifepristone may also alleviate high cortisol levels in patients with Cushing's syndrome.

Korlym® has a labeled indication for use in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and who are not candidates for surgery or who have failed surgery. Korlym® is contraindicated in pregnancy and use of mifepristone requires an evaluation of pregnancy status. Distribution of Korlym® is limited to a central pharmacy to ensure availability to Cushing's patients and their healthcare professionals.

Some references support that women who are pregnant or may become pregnant should not handle mifepristone; thus, it was added in the Hazardous Drug policy.

Korlym® was designated a high-priority nonformulary drug. Computer entries will inform prescribers that the patient must use their own supply and that it is a hazardous drug requiring special handling.

Fluticasone nasal spray will be interchanged for **beclomethasone aerosol nasal spray (Qnasl®)**. Beclomethasone is a synthetic glucocorticoid used for relieving symptoms associated with allergic or nonallergic rhinitis. Qnasl® is a nasal spray that contains 80 mcg/actuation of beclomethasone dipropionate. It differs from other formulations of beclomethasone in its dosage form (others are inhalation aerosols) and dose (other nasal sprays are 84 mcg/actuation). It is also the only formulation of beclomethasone approved for once daily administration.

In July 2010, all nasal steroids (beclomethasone, budesonide, ciclesonide, flunisolide, and triamcinolone) were designated nonformulary and not available and interchanges were approved to fluticasone nasal spray at 1 or 2 sprays per nostril once daily based on low or high doses.

Consistent with the interchanges approved previously, Qnasl® was designated nonformulary and not available with a recommended interchange to generic fluticasone 1 spray per nostril once daily. Alternatively, patients may use their own supply of Qnasl®.

Clopidogrel inhibits platelet aggregation by directly inhibiting adenosine diphosphate (ADP) binding and ADP-mediated activation of the glycoprotein GPIIb/IIIa complex. It has labeled indications for the reduction of atherothrombotic events following a recent myocardial infarction, stroke, or established peripheral vascular disease, and for acute coronary syndrome (ACS) to prevent thrombotic events.

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Formulary update, *from page 3*

It is used after percutaneous coronary interventions (PCIs) with or without stents and coronary artery bypass grafting (CABG).

Clopidogrel has a black-box warning in its labeling stating that it is dependent on the cytochrome P450 (CYP) system, specifically CYP2C19, for activation and effectiveness. Clopidogrel is a prodrug that is converted to its active metabolite by CYP2C19. "Poor" metabolizers with ACS or undergoing PCI exhibit higher cardiovascular event rates than do patients with normal CYP2C19 function, presumably because the activated metabolite is not adequately formed. Genetic tests are available to identify a patient's CYP2C19 genotype, which can be used to determine the appropriateness of clopidogrel use and whether an alternative should be considered.

The Personalized Medicine Subcommittee has focused on clopidogrel and CYP2C19 metabolism as the first clinically relevant drug and genetic testing that will use genotyping to guide clinical decision-making.

The Personalized Medicine Subcommittee recommended and the P&T Committee decided that CYP2C19 phenotypes will be reported in patients' electronic medical records based on genetic polymorphisms. Alternative therapies will be recommended when the CYP2C19 genotype suggests that clopidogrel therapy is not optimal. Specifically, the following genotype results for CYP2C19: *1, *2, *3, *4, *5, *6, *8, and *17 will be determined. In patients whose CYP2C19 genotypes suggest that clopidogrel may be suboptimal (ie, both "impaired" and "very impaired" metabolizers), prasugrel [Effient®] 10 mg daily or ticagrelor [Brilinta®] 90 mg twice daily will be recommended as possible options. The appropriate alternative will be driven by factors that prevent or limit the use of these agents. For impaired metabolizers (heterozygotes) only, increasing the dose of clopidogrel to 225 mg daily is another option.

Since insufficient clopidogrel metabolism prevents forming adequate amounts of active drug, patients who have undergone a PCI will be targeted for genetic testing.

Vasopressin is a parenteral form of antidiuretic hormone. It is utilized as a continuous infusion for various indications, including diabetes insipidus and severe hypotension in patients with cardiogenic and septic shock.

Vasopressin infusions can be ordered in EPIC via various entries. There are 2 distinct orders for pediatric infusions, which are differentiated by the above uses appearing in the order title. Confusion may arise because dosing units are different between diabetes insipidus (milliunits/kg/hour) and shock (milliunits/kg/min). Additionally, there are multiple concentrations for physicians to select from and a selection error could result in as much as a 100-fold overdose (0.01 to 1 units/mL). Overdose may also occur if a selected concentration is too high to infuse at a programmed rate in Alaris pumps.

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Formulary update, *from page 4*

In order to avoid potential adverse events, orderable concentrations of vasopressin will be only 1 standard concentration (ie, 0.01 unit/mL) for pediatric diabetes insipidus.

Desflurane is an inhaled anesthetic gas that is currently listed in the *Formulary*; however, use is restricted to outpatient surgical procedures at the Florida Surgical Center (FSC). Desflurane was re-evaluated to determine whether increased use in obese patients at Shands at UF (SUF) could be justified.

Desflurane, sevoflurane, and isoflurane are volatile liquid anesthetics that are used for general anesthesia in combination with other gases (eg, oxygen or nitrous oxide) and intravenous anesthetic agents (eg, propofol or opioids). Because patient recovery after desflurane or sevoflurane is more rapid than with isoflurane, their use has been preferred in the outpatient setting; additionally, use may be preferential in morbidly obese patients because of altered cardiopulmonary physiology and associated pathologies, including hypertension, obstructive sleep apnea, and diabetes mellitus. Morbid obesity has been shown to be an independent risk factor for difficult mask ventilation, difficult laryngoscopy, and frequent peri-operative events. For these reasons, desflurane was re-evaluated for use in morbidly obese patients at SUF.

Desflurane, unlike sevoflurane and isoflurane, cannot be used for mask induction, since it is too irritating to the respiratory system. Thus, another agent must be used instead for induction (eg, propofol).

The use of desflurane in morbidly obese patients has been associated with similar outcomes reported in the literature seen with the use of sevoflurane, including quicker time to recovery, shorter length of operating room (OR) stay, post-anesthesia care unit (PACU) stay, and overall hospital stay when compared to isoflurane. However, it is unclear whether desflurane has additional benefit over sevoflurane concerning these outcomes. Quicker time to recovery and shorter length of OR stay have been observed. These differences are modest, resulting in differences of a few minutes. Whether these differences are clinically significant is debatable.

In general, the adverse effects associated with desflurane are the same as those associated with isoflurane or sevoflurane. Like all other inhaled anesthetic gases, desflurane is associated with more nausea and vomiting than propofol; however, the incidence of post-operative nausea and vomiting (PONV) appears similar between desflurane and sevoflurane. Desflurane is the most pungent agent, with respiratory irritation seen above 1 MAC. At low flow rates, there is concern about nephrotoxicity with sevoflurane because of a fluorinated metabolite called Compound A (fluoromethyl-2,2-difluoro-1-[trifluoromethyl] vinyl ether); however, there are no reports of Compound A toxicity in humans.

Independent assessments of cost suggest that desflurane is more expensive than sevoflurane and isoflurane. Desflurane is only available from a single vendor and requires

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Sunscreens, from page 1

a special vaporizer for administration, which makes it more expensive. Despite low flow rates, desflurane costs still exceed the costs of sevoflurane.

After considering the increased cost and the unlikely ability for the small benefit to translate to clinically meaningful differences in outcomes, no changes were made to the current desflurane criteria for use.

If we use sunscreens to prevent skin aging and decrease the risk of cancer, are we increasing our risk of vitamin D deficiency? Adequate amounts of vitamin D are necessary for strong bones, but vitamin D may have other beneficial health effects. Older guidelines recommended exposure of the arms and legs to 5 to 30 minutes of sunlight (UVB radiation) between 10 AM and 3 PM twice a week, which was estimated to be sufficient to form adequate amounts of vitamin D in the skin. If we avoid the sun and/or block too much UVB radiation, are we contributing to vitamin D deficiency?

Current evidence does not support this concern. Studies do not show decreased levels of vitamin D or effects on other metabolic markers of vitamin D deficiency with sunscreen use. These studies are limited however. Studies have not adequately examined the higher SPF, broad-spectrum, water-resistant products. There are concerns about vitamin D deficiency, in general, regardless of the effects of sunscreens.

Therefore, supplementation with oral vitamin D_3 capsules (cholecalciferol) 1000 units per day should be considered. This amount is often used for patients who do not get sufficient sun exposure, and poses little risk. Taking a supplement is preferable to increasing your sunlight exposure to get adequate vitamin D. Although very few foods naturally contain vitamin D (eg, fish like tuna or salmon), some foods are fortified with vitamin D like milk, yogurt, margarine, cheese, and cereals. Some patients may get sufficient vitamin D from their diet.

Avoiding the mid-day sun is always best, but we cannot always be inside during midday. Frequent and appropriate use of a sunscreen with a SPF of 50 or greater that is broad-spectrum and water-resistant should help minimize the damaging effects of the sun. If you are concerned about getting an adequate amount of vitamin D, consider increasing the amount of vitamin D in your diet or taking a daily vitamin D dietary supplement.

Drug information questions?

Contact the Drug Information Service

Call 265-0408

Or submit your question online at www.shands.org/professionals/druginfo/default.asp

- This service is for referring physicians and other healthcare professionals taking care of Shands patients
- Phones are staffed from 9 am to 4:30 pm, Monday – Friday
- All answers are thoroughly researched and referenced

For emergent questions that do not need thorough research, go to the pharmacy servicing your area.