Volume 27, Number 5

Shands at the University of Florida

May 2013

Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met April 16, 2013. No drugs were added in the *Formulary*, 2 drugs were deleted, and 5 drugs were designated nonformulary and not available. 2 interchanges were approved and 4 drugs had criteria for use changes.

◆ ADDED

None

◆ DELETED

Amyl Nitrite Ampule/Inhalant (Generic)*

Sildenafil 25-mg Tablets* (Viagra®)*

**Nonformulary and not available; interchanged to 20-mg*

◆ NONFORMULARY AND NOT AVAILABLE

Carfilzomib (Kyprolis®)*

**May be used in the BMT Outpatient Clinic & Infusion Center*

Clozapine Suspension (Versacloz®)

Crofelemer (Fulyzaq®)*

**Patients may use their own supply*

Hydrocodone-Chlorpheniramine (Vituz®)

Ospemifene (Osphena®)*

**CANNOT USE IN INPATIENT SETTING*

◆ INTERCHANGES

Oral Phosphate for **IV Phosphate**

Sildenafil 20-mg (Generic) for **Sildenafil 25-mg** (Viagra®)

◆ CRITERIA-FOR-USE CHANGES

Acetaminophen IV (Ofirmev®)‡

‡Neutropenic fever when the oral route is unavailable

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PRESCRIBING

The route less traveled

The rectal route of administration is underused. The "per rectum" (PR) route offers a convenient and cost effective option. There are few true contraindications. A drug's route of administration is limited by the formulations available. Formulations are dependent on the innate physical and chemical properties of drugs.

By mouth or "per os" (PO) is the most common route of drug administration. Most currently approved drugs are administered PO, either as a solid oral dosage form (eg, capsule or tablet), orally disintegrating tablet, buccal or sublingual route, or as an oral liquid. These drugs are convenient, can be self-administered, and are often less expensive compared to parenteral (ie, "nonenteral") routes.

However, some oral drugs are susceptible to first-pass effect, which can reduce bioavailability. The properties of the active ingredients may not withstand stomach acid. In emergent situations, the onset of action may be too slow or not practical in an unconscious patient.

Alternative routes of drug administration include transdermal, parenteral, nasal, and rectal. The transdermal route can increase compliance but can cause dermatitis. Adverse events can occur when patches are not removed before placing a new patch. Parenteral agents are convenient and have a quick onset of action. Obtaining intravenous access can be a challenge, and can lead to infection.

The rectal route of administration is underused and underappreciated. Few drugs can be administered rectally and are overlooked as therapeutic options. These drugs are capable of providing local effects or achieving systemic concentrations, usually within 5 to 30 minutes.

The rectal route is ideal when other routes are impractical or not feasible. It is preferred in patients who have nausea, vomiting, or esophageal obstruction. This also applies to patients that are unconscious or uncooperative. Children are frequently administered drugs rectally, especially when the oral liquid formulation tastes unpleasant.

Seizures are an emergent situation when the rectal route is an alternative to an injection, if patients are not hospitalized. Diazepam is available in a gel formulation that is instilled rectally using a prefilled syringe.

Terminally ill patients commonly lose their ability to take drugs orally. This can be due to absorptive impairment, mental status changes, or an obstruction. Utilizing the rectal route can ensure adequate pain control, minimize adverse effects, and maximize comfort.

One of the concerns from health care professionals is the perception that rectal absorption is erratic. Drug absorption may be delayed or prolonged as the rate of rectal absorption is affected by several factors. The formulation determines the time to liquification of the suppository. The rate is also affected by the volume, retention, and the concentration of the suppository. Data are lacking that show the variability in absorption impacts therapeutic outcomes.

Is the rectal route less effective or is the effect delayed? A study by Karbasi and colleagues compared the effectiveness of oral and rectal acetaminophen as an antipyretic in 60 febrile children. Children aged 6 months to 6 years who presented to an emergency department were randomly assigned to receive 15 mg/kg acetaminophen rectally or the same dose orally. Temperature was recorded at baseline and 1 and 3 hours after administration. In the rectal group, mean decrease in temperature, 1 and 3 hours after administration of acetaminophen, was 1.1˚C and 1.7˚C, respectively, and in the oral group it was 2.0˚C and 1.7˚C, respectively. Based on this study and other similar studies that have been conducted, rectal and oral acetaminophen preparations have similar antipyretic effectiveness.

IV promethazine is associated with significant adverse effects. The Institute

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INSIDE THIS ISSUE

Formulary update, *from page 1*

Ado-trastuzumab (Kadcyla®)†

†*Added in the Chemotherapy Policy*

Methadone (Generic)§

§*Restrictions modified*

Phosphate IV (Generic)§

§*Restricted*

Amyl nitrite is a rapidly acting vasodilator administered by inhalation. A nonspecific smooth muscle relaxant, it is used for its prominent effect on vascular smooth muscle. The primary user of amyl nitrite has been the Echocardiography Lab, which has been notified that this product is no longer available. Amyl nitrite has been used in echocardiography to measure provocable left ventricular outflow obstruction.

Amyl nitrate is very flammable, which requires special storage. Diversion is also an issue because amyl nitrite can be used to cause euphoria (ie, "poppers"). Amyl nitrite has been used with drugs of abuse.

It has also been used as an antidote for cyanide poisoning. It was a component of the Cyanide Antidote Kit, which was deleted from the *Formulary* in 2007. It induces methemoglobinemia, which can sequester cyanide. Hydroxocobalamin (Cyanokit®) is listed in the *Formulary* for cyanide poisonings.

The only supplier of amyl nitrite ampules for inhalation has discontinued making this product, so it was deleted from the *Formulary* and is not available for nonformulary use.

Sildenafil is a phosphodiesterase inhibitor that was first approved in 1998 for erectile dysfunction as Viagra®. In 2005, Revatio® was approved for the treatment of pulmonary arterial hypertension.

The P&T Committee has previously determined that the 20-mg and 25-mg doses of sildenafil are equivalent. When Revatio® (20-mg) was marketed, Viagra® and Revatio® were the same cost, and interchange was not considered. Revatio® is now available as a generic, while the 25-mg dosage form of Viagra® remains on patent.

The cost savings of using generic Revatio® is approximately $23 per tablet. For this reason and equivalent efficacy, the 25-mg dose was deleted from the *Formulary* and will be interchanged to 20-mg.

Carfilzomib is a proteasome inhibitor with a labeled indication for the treatment of multiple myeloma in patients who have received at least 2 prior treatment regimens and have disease progression within 60 days of the most recent treatment. Carfilzomib had been added to the *Chemotherapy Policy*, but its formulary status had not been addressed.

Carfilzomib is a potent, selective, and irreversible proteasome inhibitor with antiproliferative and proapoptotic activity in multiple myeloma. The drug received its indication in relapsed or refractory myeloma based on a phase II single agent trial of 266 patients with progressive myeloma. All patients were responsive to at least 1 prior regimen and refractory to their most recent therapy; all patients must have also received greater than or equal to 2 prior regimens for relapsed disease. Overall response rate was 23.7% with a median response duration of 7.8 months. Median overall survival was 15.6 months.

Carfilzomib is administered intravenously over 2 to 10 minutes on 2 consecutive days each week for 3 weeks (days 1, 2, 8, 9, 15, 16). This is followed by a 12-day rest period (days 17-28); each 28-day period is 1 treatment cycle. During cycle 1, carfilzomib is administered at a dose of 20 mg/m^2. If tolerated, the dose is escalated to 27 mg/m^2 in cycle 2 and continued at 27 mg/m^2 in subsequent cycles. Carfilzomib treatment may be continued until disease progression or until unacceptable toxicity.

There are no contraindications or boxed warnings for carfilzomib. The most common adverse reactions noted in clinical trials were fatigue, anemia, nausea, thrombocytopenia, dyspnea, diarrhea, and pyrexia. There are warnings for cardiac arrest, congestive heart failure, myocardial ischemia, pulmonary complications, infusion reactions, tumor lysis syndrome, thrombocytopenia, and hepatic toxicity and failure.

Carfilzomib costs approximately $10,000 for the first cycle.

Carfilzomib was designated nonformulary and not available for inpatient use. It is available for use in the Infusion Center.

Versacloz® is an **oral suspension** of the atypical antipsychotic agent **clozapine**. The orally disintegrating (ODT) dosage form of clozapine (Fazaclo®) was designated nonformulary and not available in October 2005.

Clozapine tablets are listed in the *Formulary*. They are only available for use via a restricted-distribution system, but they can be purchased for use in the inpatient setting. Since approximately 1% of patients can develop agranulocytosis, periodic white blood cell counts are needed to assure safe use. Current policy assures safe use of clozapine consistent with its required restrictions.

Crofelemer, derived from the red sap of the *Croton lechleri* plant, is the second botanical prescription drug approved by the FDA. A botanical drug product is often a complex mixture derived from one or more plant materials with varying degrees of purification. Manufacturers of a botanical drug product must ensure rigorous control of raw materials, and good agricultural and collection practices, together with analytical testing of the final product.

Crofelemer is an antidiarrheal with a labeled indication for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. The proposed mechanism of action is local in the gut by decreasing gastrointestinal fluid accumulation. By inhibiting the secretion of chloride ions via the cystic fibrosis transmembrane regulator chloride channels and the calcium activated chloride channels of the luminal membrane of intestinal cells fluid secretion is decreased.

Diarrhea is experienced by many HIV/AIDS patients and is a common reason why patients discontinue or switch their antiretroviral therapies. Patients take crofelemer 2 times a day to manage watery diarrhea due to the secretion of electrolytes and water in the gastrointestinal tract.

The safety of crofelemer was established in placebo-controlled trials involving 696 patients. There were 374 HIV-positive patients on stable antiretroviral therapy with a history of diarrhea lasting 1 month or longer enrolled in the ADVENT efficacy trial. The baseline median number of watery bowel movements was 2.5 per day. Patients who had diarrhea caused by an infection or a gastrointestinal disease were excluded from participating in the trials. The trial was designed to measure clinical response, defined as the number of patients who had 2 or fewer watery bowel movements weekly. Results showed that 17.6% of patients taking crofelemer experienced clinical response compared with 8% taking placebo. In some patients, a persistent antidiarrheal effect was seen for 20 weeks. No dose modifications are recommended with respect to CD4 cell count and HIV viral load, based on the findings in subgroups of patients defined by CD4 cell count and HIV viral load. Among race subgroups, there were no differences in the consistency of the crofelemer treatment effect except for the subgroup of African-Americans; crofelemer was less effective in African-Americans than non-African-Americans. The safety and effectiveness of crofelemer have not been established in pediatric patients less than 18 years of age. Before treating patients with crofelemer, health care professionals should conduct proper testing to confirm the diarrhea is not caused by an infection or a gastrointestinal disease. If infectious etiologies are not considered, and crofelemer is initiated based on a presumptive diagnosis of non-infectious diarrhea, then there is a risk that patients with infectious etiologies will not receive the appropriate treatments, and their disease may worsen.

Common adverse effects reported in

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Formulary update, *from page 2*

patients taking crofelemer in the clinical trial were upper respiratory tract infection, bronchitis, cough, flatulence, and increased levels of the liver enzyme bilirubin.

Crofelemer has been investigated for several secretory diarrhea indications including diarrhea-predominant irritable bowel syndrome, acute infectious diarrhea, and pediatric diarrhea. Off-label use is a concern.

Crofelemer was designated nonformulary and not available; patients will use their own supply from home.

Vituz® is a combination of an opioid (**hydrocodone**) and an antihistamine (**chlorpheniramine**) with a labeled indication for the relief of cough and symptoms associated with upper respiratory allergies or the common cold. This combination drug is a Schedule III controlled substance.

In August 2011, the P&T Committee designated Rezira® (hydrocodone-pseudoephedrine) and Zutripro® (hydrocodone-pseudoephedrine-chlorpheniramine) nonformulary and not available.

There are currently no hydrocodone-containing products listed in the *Formulary*. Since this is a controlled substance, patients may not use their own supply. Vituz® was designated nonformulary and not available.

Ospemifene is an estrogen agonist/antagonist with a labeled indication for the treatment of moderate to severe dyspareunia. Dyspareunia is a condition associated with declining levels of estrogen in menopause. Lower estrogen levels lead to thinner vaginal tissue that is drier and more fragile.

Ospemifene is a tablet taken with food once a day. It acts like estrogen to thicken vaginal tissue and make it less fragile.

Ospemifene's efficacy was established in 3 placebo-controlled, clinical studies of 1,889 post-menopausal women with symptoms of vulvar and vaginal atrophy. After 12 weeks of treatment, the first 2 studies showed a statistically significant improvement in dyspareunia in ospemifene-treated women. The third study is a long-term study designed to look at safety.

Ospemifene has a boxed-warning alerting women and healthcare professionals that thickening of the endometrium occurs. Since postmenopausal women no longer menstruate, this can be problematic. Unusual vaginal bleeding may be a sign of endometrial cancer or a condition that can lead to it. Ospemifene should be prescribed for the shortest duration consistent with treatment goals and risk for the individual woman.

The boxed-warning also notes the incidence of thrombotic and hemorrhagic strokes and the incidence of deep venous thrombosis (DVT). These rates appear low compared with the risks associated with estrogen alone.

Common adverse effects include hot flushes/flashes, vaginal discharge, muscle spasms, and excessive sweating.

Ospemifene was designated nonformulary and do not use for possible safety reasons.

A critical shortage of **intravenous potassium** and **sodium phosphate** required dramatic restrictions on their use. Prescribers have been receiving Epic alerts suggesting oral alternatives, and oral use increased. The alerts and occasional shipments of limited supplies had mitigated the shortage. However, we are now in "emergency mode." Without further restrictions, we will exhaust all parenteral phosphate supplies. We currently have no potassium phosphate, and an extremely short supply of sodium phosphate.

Alerts have been successful at encouraging oral phosphate use, but there has been confusion about how to convert IV to oral formulations. Typically, prescribers convert 1:1, but if bioavailability and tolerability issues are considered, the table below is recommended.

With a subsequent decline in supply and increased use of IV phosphate, the following restrictions were adopted: sodium phosphate therapy during CRRT; phosphate replacement in any patient with a serum phosphorous below 1; and, phosphate replacement in any patient with a serum phosphorous 1 to 1.5 where no other oral or enteral medications are currently prescribed.

The use of premixed parenteral nutrition formulas will be used to extend supplies of parenteral phosphate. About a third of our parenteral phosphate supplies are used to compound parenteral nutrition.

Compounded parenteral phosphate is still an option. A supply of sterile parenteral phosphate compounded from nonsterile ingredients has been ordered and will be available in early May.

Intravenous (IV) acetaminophen was added to the *Formulary* in June 2011 and restricted to post-operative use up to 24 hours and as a single dose in the ED. Further restrictions include no "as needed" (PRN) orders, no inclusion in Epic order sets (except in the PACU), and only dosage regimens for every-6-hour intervals in adults and children (ie, no every-4-hour regimens). Also, it was added in the *IV-to-PO Policy* permitting conversion to an oral or enteral dosage form when other medications are being given orally or enterally.

A medication use evaluation was done to evaluate adherence to IV acetaminophen criteria for use. Random samples of adult and pediatric patients admitted between June and December 2011 were evaluated. Five of 10 (50%) pediatric and 6 of 50 (12%) adult patients met criteria for use. Opportunities for improvement include more use of the rectal (PR) route, strict enforcement of the *IV-to-PO Policy* in patients receiving oral medications, and strict enforcement of the restrictions on use beyond 24 hours post-operatively.

Only 2 patients in the sample were neutropenic (which precludes PR administration), approximately 80% of patients received oral medications, and 26% of orders occurred beyond the 24-hour post-operative window. Adding another criterion that would allow the "as needed" use of IV acetaminophen in patients with severe mucositis (unable to take oral medications) and who are neutropenic (so unable to take rectal medications) was considered.

The IV acetaminophen criteria were modified to include, "fever with severe mucositis and neutropenia." There will be a note to call pharmacy

IV Phosphate	Equivalent PO Phosphate	K Phos Neutral Tablets (8 mmol phosphate, 1.1 mEq potassium, 13 mEq sodium per tablet)	Phosphate Oral Liquid (3 mmol phosphate and 4.4 mEq potassium per mL)	Sodium Phosphate Oral Liquid (4.1 mmol phosphate and 4.8 mEq sodium per mL)
9 mmol	13.5 mmol	2 tablets x 1	13.5 mmol (4.5 mL) x 1	13.5 mmol (3.3 mL) x 1
15 mmol	22.5 mmol	1 tablet Q 6 hrs x 3	7.5 mmol (2.5 mL) Q 6 hrs x 3	11.5 mmol (2.8 mL) Q 6 hrs x 2
24 mmol	36 mmol	1.5 tablets Q 6 hrs x 3	9 mmol (3 mL) Q 6 hrs x 4	18 mmol (4.4 mL) Q 6 hrs x 2
30 mmol	45 mmol	2 tablets Q 6 hrs x 3	15 mmol (5 mL) Q 6 hrs x 3	14.8 mmol (3.6 mL) Q 6 hrs x 3
Oral absorption of phosphate product is approximately 66%				

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Formulary update, *from page 3*

to enter a maintenance order for this indication. For this use only, "as needed" dosing will be allowed.

Ado-trastuzumab is a HER2-targeted antibody and microtubule inhibitor conjugate with a labeled indication for the treatment of patients with HER2-positive metastatic breast cancer as a single agent after patients have received trastuzumab and a taxane, separately or in combination. Ado-trastuzumab was referred to as T-DM1 during clinical research. The generic name is ado-trastuzumab in an attempt to avoid medication errors by confusing trastuzumab (Herceptin®) with ado-trastuzumab.

Ado-trastuzumab has a boxed warning alerting patients and healthcare professionals that the drug can cause liver toxicity, heart toxicity, and death. It can also cause severe life-threatening birth defects, and pregnancy status should be verified prior to starting ado-trastuzumab treatment.

Ado-trastuzumab was added in the *Chemotherapy Policy*. It will be proactively reviewed to determine its formulary status.

Methadone is a potent synthetic opioid that is difficult to use safely. Methadone has a boxed warning stating that methadone use for acute or chronic pain should be initiated only if the potential benefits outweigh the risks. For these reasons, it has been restricted in both adult and pediatric patients.

Methadone restrictions were modified to address conflicts between the pediatric and adult criteria for use. The goal is to limit methadone use to prescribers who can safely prescribe it.

The following revised methadone criteria were developed. All orders for methadone must include the indication for use, regardless of age. Methadone will not be used for acute pain.

Use in pediatric patients (less than or equal to 18 years of age) on a pediatric unit for iatrogenic withdrawal would be limited to a standard order set that will note the attending physician approving the use of methadone and dose. Pediatric patients in adult units will follow adult restrictions. Pediatric use for pain will be approved by a Hematology-Oncology progress note. Continuation of a home regimen for opioid addiction is allowed.

For patients greater than 18 years of age, methadone will not be included in any order set. Continuation of a home regimen for the treatment of opioid addiction continues to be acceptable. Continuation of a home regimen for chronic or cancer pain is allowed. The prehospitalization dosage must be verified, and the dose cannot be modified. The initiation for the treatment of withdrawal symptoms requires an Addiction Medicine or Psychiatry consult and approval. This use is permissible, but should rarely be used. Initiation for chronic or cancer pain [or modification of an existing dose] requires approval by the Inpatient Pain Service, Palliative Care Service, or the Chief of Pain Medicine or his/her designee.

POLICIES AND PROCEDURES

High-priority, restricted-distribution drugs

In last month's *Bulletin*, various formulary and nonformulary categories were reviewed. The term *restricted drug distribution program* was used, and some readers of the *Bulletin* were not familiar with this term.

Restricted drug distribution programs [or systems] are methods used by drug companies to limit access to drugs, primarily for safety reasons.[1-5] These agents are sometimes called "limited distribution drugs." The restrictions or limitations fall under the FDA's Risk Evaluation and Mitigation Strategies (REMS). Restricting drug access has a long history, and this article briefly explains these heterogeneous programs.

When these programs were last reviewed in the *Bulletin* in 2003, the legal authority to restrict access to FDA approved drugs was questionable.[3] In 2007, legal authority was given by the FDA Amendments Act (FDAAA) by establishing REMS, which allows for "restrictions on distribution."

Prior to 2007, a small number of drugs that offered substantial therapeutic benefits, but significantly increased risks relative to most drugs in that therapeutic area were available only by restriction distribution.[3] Clozapine was an early example of this.

Clozapine is still the gold standard for treatment-resistant schizophrenia. In early clinical trials, it was estimated that approximately 1% of patients treated with clozapine developed agranulocytosis. Drugs usually never make the market when 1 in 100 patients are at risk of dying. Yet, in treatment-resistant patients who have white blood cells (WBCs) monitored closely, it can be used safely and provide relief for patients who do not respond to less risky options.

Clozapine was only dispensed in small amounts after the patient provided a blood sample that showed that they were tolerating therapy. This "blood for drug" program prevented patients from from a fatal adverse effect, while treating their condition. If clozapine was stopped before WBCs dropped too far, the adverse effect was reversible.

Many restricted drug distribution systems are administered by specialty pharmacies like Accredo, Caremark, or CuraScript. These pharmacies limit their activities to high cost/low volume drugs that are often "high profit" and/or "high risk." Low patient volumes allow more time to monitor the restrictions placed on the drugs before they are delivered to patients.

Not all restricted drug distribution programs are limited to specific pharmacies. For example, any pharmacy willing to abide by the clozapine restrictions can dispense this drug.

The safety checks might require special laboratory testing (eg, pregnancy testing for a Category X teratogen) or diagnostic criteria.

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Drugs & Therapy
B · U · L · L · E · T · I · N

Volume 27, No. 5 May 2013
This publication is produced by the Drug Information and Pharmacy Resource Center under the direction of the Department of Pharmacy Services and the Pharmacy and Therapeutics Committee.

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Rectal Dose Administration, *from page 1*

for Safe Medication Practices issued an alert warning health care professionals of the risk of promethazine causing damage to blood vessels and surrounding tissues. Using promethazine suppositories avoids this complication. A study performed in 99 post-operative adults evaluated the efficacy of rectal promethazine. After discharge, 55% of patients experienced nausea. Of these, 48% subsequently used the suppository, all of which reported some or great improvement in symptoms. Investigators found that suppositories were effective in treating post-operative nausea and vomiting.

There are scenarios when the rectal route of drug administration should be avoided. Neutropenic patients are at high risk for the development of infection and should not receive drugs rectally. This may introduce bacteria into the bloodstream and cause sepsis. Patients with thrombocytopenia are also perceived to be at increased risk of harm. Active diarrhea would preclude the use of these agents…for obvious reasons.

by Janet Arrazcaeta, PharmD

References available upon request from the Editor.

Restricted Distribution Systems, *from page 5*

They often require that patients receive a Medication Guide, which helps patients better understand the risks associated with taking a drug.[6] The program may also require registration and training of the prescribers and pharmacies. These restrictions are not voluntary, and the manufacturer is held accountable for compliance with any REMS, including the restricted distribution.

Most restricted distribution systems are designed for outpatient use of drugs. Too often, these programs are not well designed for inpatient use of drugs. The program for alvimopan (EASE) restricts the use of the drug to the inpatient setting, but most do not focus on inpatient use. For this reason, patients may have to use their own supply while they are hospitalized… even if the drug is an injectable. Depending on the program, they may not allow a hospital to purchase product. The manufacturer is trying to limit the use of a product to specific patients and specific prescribers.

One challenge with restricted distribution programs is that they change. As the number of these restricted distribution programs increases, keeping current with all requirements is difficult.

References available upon request from the Editor.

TABLE. SELECTED RESTRICTED DRUG DISTRIBUTION PROGRAMS

Cayston® Access Program
Clozaril® Administration Registry Enrollment (CARE)
Entereg® Access Support and Education (EASE)
Gattex® REMS
iPLEDGE (isotretinoin)
OneSource (Soliris®)
Pomalyst® REMS
Revlimid® REMS
Support, Help, And Resources for Epilepsy (SHARE) for Sabril®
Support Program for Access and Reimbursement for Korlym® (SPARK)
System for Thalidomide Education and Prescribing Safety (STEPS)
Tikosyn® in Pharmacy Systems (TIPS)
Tracleer® Access Program (TAP)
Transmucosal Immediate Release Fentanyl (TIRF) REMS
Tysabri® Outreach Unified Commitment for Health (TOUCH)
Xolair® Access Solutions
Xyrem® Success Program