

# Drugs & Therapy

B • U • L • L • E • T • I • N

## FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met October 18, 2011. 5 products were added in the *Formulary*, and 3 were deleted. 5 products were designated nonformulary and not available. 1 interchange and 5 criteria for use were approved.

### ◆ ADDED

#### Carbidopa (Lodosyn®)\*

\*Restricted: patients on levodopa

#### Ertapenem (Invanz®)\*

\*Restricted: ID or the Antimicrobial Management Program approval

#### Meloxicam (Generic)

#### Micafungin (Mycamine®)\*

\*Restricted: ID or the Antimicrobial Management Program approval

#### Ticagrelor (Brilinta®)

### ◆ DELETED

#### Anidulafungin (Eraxis®)†

#### Cellulase Powder (Generic)†

#### Mupirocin Nasal Ointment (Bactroban® Nasal Ointment)†

†Nonformulary and Not Available

### ◆ NONFORMULARY AND NOT AVAILABLE

#### Tapentadol Immediate-Release (Nucynta®)

#### Tapentadol Extended-Release (Nucynta® ER)

### ◆ INTERCHANGES

#### Generic Tacrolimus for Prograf®

### ◆ CRITERIA-FOR-USE CHANGES

#### Amphotericin B Deoxycholate (Generic)\*

\*Can be used only for bladder irrigations, inhaled, etc.

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## P&T COMMITTEE

### The *Formulary* and the P&T Committee

There are times when a hospital formulary may be seen by a practicing clinician as an unnecessary and burdensome limitation of his prescribing practices. Occasionally the exclusion of a favored product from a hospital formulary may be taken as a personal affront and regarded as a criticism of the physician's clinical judgment and practice.

Indeed the *Formulary* and its associated committee have been invoked from time to time as evidence of the modern encroachment upon personal liberty by an autocratic administrative bureaucracy. Many questions may be asked about it—for the *Formulary* and the committee are often combined under the pronoun, "it." The questions often include: *Why does it exist; What does it do; When does it do it; and, Who is it?* There may be merit in mentioning some of the facts about the *Formulary* and Pharmacy and Therapeutics Committee.

The formulary system and hospital formularies have existed since the days of the American Revolution. It became quite commonplace for hospitals to compile formularies. However, a hospital formulary did not solve all problems, and a hospital pharmacy director found himself without specific responsibilities or privileges to resolve the many difficulties connected with this task. More often than not, he had to resolve a problem by personal appeal to the particular physician or administrator involved. The need for a more systematic, effective system of communication between hospital administrators, pharmacists, and prescribing physicians led to the establishing of formal pharmacy and therapeutics committees.

Who is it? Representatives from different medical departments are selected to give a broad coverage of the various divisions of practice. Members of the committee are expected to take their task seriously, to attend meetings regularly, and to accept special assignments when problems arise.

What does it do? The committee is designed to make maximum use of the

available professional skills and judgment. It serves as the organizational line of communication or liaison between the medical staff and the hospital regarding all drug-related matters. It assists in the formulation of broad professional policies regarding the evaluation, selection, procurement, distribution, use, safety procedures, and other matters relating to drugs in the hospital.

A primary function is to recommend drugs that should be available in the hospital pharmacy. To this end, it has compiled a hospital formulary. The *Formulary*, by listing the preferred drugs in each category, makes it possible to operate safely with the greatest efficiency and at the lowest cost.

The list of drugs in the *Formulary* must be constantly kept up-to-date by the addition of new drugs and the deletion of drugs that have become obsolete or, even though useful, are replaced by new drugs with greater therapeutic effect or fewer adverse reactions. When all else is equal, the comparative cost of comparable drugs may be an influencing factor.

An attending physician may prescribe a drug not in the *Formulary*. This enables the physician to prescribe a particular nonformulary drug that may be appropriate under certain circumstances. It also provides an opportunity for teaching the housestaff. The attending physician can discuss the relative merits and demerits of the drug in question versus other drugs that might be used for the same purpose that may be in the *Formulary*.

When and how does it do it? The Pharmacy and Therapeutics Committee meets at regular intervals, usually once a month. The committee, as far as possible, bases its decisions on the objective evidence that is available.

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◆ **CRITERIA-FOR-USE CHANGES (CONT.)**

**Ampicillin-Sulbactam (Unasyn®)\***

\*Restricted: ID or Antimicrobial Management Program Approval Required after 72 hours

**Citalopram (Generic)\***

\*Doses above 40 mg not recommended

**Crizotinib (Xalkori®)\***

\*Added in the Chemotherapy Policy

**Ticarcillin-Clavulanate (Timentin®)**

\*Restricted: ID or the Antimicrobial Management Program approval

**Carbidopa** was evaluated proactively because of relatively frequent nonformulary use. Carbidopa is an inhibitor of aromatic amino acid decarboxylation and has labeled indications for use with levodopa in the treatment of the symptoms of idiopathic Parkinson's disease, postencephalitic parkinsonism, and asymptomatic parkinsonism that may follow injury to the nervous system by carbon monoxide intoxication and/or manganese intoxication. Since Parkinson's disease symptoms are related to the depletion of dopamine in the corpus striatum, levodopa is given to correct this deficiency. Dopamine does not cross the blood-brain barrier; levodopa, the metabolic precursor to dopamine, does cross the blood-brain barrier where it is converted to dopamine.

Carbidopa inhibits the decarboxylation of levodopa in the periphery. It does not have any overt pharmacodynamic actions in the recommended doses. It does not cross the blood-brain barrier and does not affect the metabolism of levodopa in the central nervous system.

Fixed-dose combinations of levodopa and carbidopa are common (eg, Sinemet®) and levodopa is not available by itself. Carbidopa is used with levodopa in the occasional patient whose dosage requirement of carbidopa and levodopa necessitates separate titration of carbidopa.

Carbidopa was added in the *Formulary* and restricted to patients already taking levodopa [and carbidopa].

**Ertapenem** is a once-daily, broad-spectrum carbapenem antimicrobial agent with a labeled indication for the treatment of community-acquired pneumonia, complicated intra-abdominal, complicated skin and skin-structure, complicated urinary tract, and acute pelvic infections. This property enables it to be the first carbapenem antibiotic that is indicated for once-daily dosing.

Ertapenem is highly active *in vitro* against methicillin-susceptible staphylococci, most streptococci, Enterobacteriaceae, and Gram-positive and Gram-negative anaerobes. Unlike imipenem and meropenem, ertapenem has limited activity against *Pseudomonas aeruginosa* and other nonfermentative Gram-negative bacilli. None of the carbapenems is considered first-line therapy against enterococci, but of the 3, ertapenem is the least active *in vitro*.

Several clinical trials have been conducted comparing the efficacy of ertapenem against other agents in managing complicated intra-abdominal, pulmonary, skin and soft tissue, and urinary tract infections. In all comparative trials, ceftriaxone, either with or without metronidazole, or piperacillin/tazobactam, served as the comparator agent. Of note, these trials were powered to demonstrate equivalence of ertapenem with other agents, not superiority. Overall, ertapenem was found to have similar cure rates as standard therapy in each of the specified disease states. In addition, for patients with infections associated with extended-spectrum beta-lactamase (ESBL) producing organisms, ertapenem has been shown to be an effective alternative with minimal impact on carbapenem susceptibility in other organisms.

Since ertapenem does not have appreciable activity against *Pseudomonas* with sufficient activity against ESBL-producing bacteria, it was added in the *Formulary* and restricted to approval by Infectious Diseases or the Antimicrobial Management Program for use in the management of cefepime-resistant, ESBL-producing bacteria.

**Meloxicam** is a generic nonsteroidal anti-inflammatory drug that was added in the *Formulary* in January 2010 for use at Shands Rehab Hospital as an alternative to celecoxib (Celebrex®). It is relatively COX-2 selective, like celecoxib, and considerably less expensive.

Many patients are admitted to Shands at UF receiving this drug, which has required switching to another agent. Meloxicam was added in the *Formulary* at Shands at UF without restrictions.

**Micafungin** is an echinocandin antifungal that was added in the *Formulary* to replace **anidulafungin**. In 2007, the P&T Committee approved the addition of anidulafungin in the *Formulary* as the echinocandin of choice with restriction to approval by Infectious Diseases or the Antibiotic Management Program. The decision was based on the conclusion that these agents were equally effective and that the most cost-effective option should be selected.

In 2008, some members of the Pediatric Department expressed concerns over the lack of data supporting the use of anidulafungin in children less than 2

years old. The safety and efficacy of anidulafungin in pediatric patients had not been established. There were no published pharmacokinetic or clinical data addressing dosing in children less than 2 years old to include neonates. There were published data supporting the use of caspofungin in children less than 2 years of age to include neonates at doses of 1 to 2 mg/kg/day. Since its approval in 2001, caspofungin had been used in pediatric patients less than 2 years of age at Shands at UF and Shands AGH. Therefore, caspofungin was added in the *Formulary* but was restricted to use in pediatric patients less than 2 years of age. In addition, its use was restricted to approval by Pediatric Infectious Diseases or clinical pharmacists.

Micafungin is now considerably less expensive than anidulafungin or caspofungin. Therefore, it is now the primary echinocandin listed in the *Formulary*. Micafungin may be used for the following:

- Treatment of oropharyngeal/esophageal candidiasis refractory or intolerant to other antifungal therapy (azoles and amphotericin B products).
- Treatment of *Candida* fungemia in patients refractory after 7 days of therapy with other antifungal therapy (azoles or amphotericin B products).
- Treatment of *Candida* fungemia in patients with a documented or at risk for resistant *Candida* spp.
- Alternative to lipid amphotericin B products in the treatment of candidiasis in patients who have met criteria to receive lipid amphotericin B products.
- Salvage therapy for invasive aspergillosis in patients that do not tolerate voriconazole or lipid amphotericin B products.
- Treatment of probable or definite aspergillosis in patients who are refractory (ie, stable disease or disease progression based on CT scan findings) to 14 days of therapy with voriconazole or amphotericin B products or patients who have progression of disease after 7 days of voriconazole or amphotericin B therapy.
- Not routinely indicated for the treatment of *Candida* sp isolated from respiratory samples. *Candida* lower respiratory tract infection is rare and requires histopathologic evidence to confirm a diagnosis.

**Ticagrelor** is a reversible, direct acting P2Y<sub>12</sub> platelet inhibitor with a labeled indication to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (ie, unstable angina, non-ST

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**Formulary update, from page 2** elevation myocardial infarction, or ST-elevation myocardial infarction). According to its labeling, ticagrelor has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction, or stroke compared to clopidogrel (Plavix®). The difference between treatments was driven by cardiovascular death and myocardial infarction (MI) with no difference in stroke. In patients treated with percutaneous coronary interventions, it also reduces the rate of stent thrombosis. It is anticipated that clopidogrel will remain the primary agent used.

Ticagrelor's direct-acting and reversible binding to the P2Y<sub>12</sub> receptor has been shown to have a stronger and more rapid antiplatelet effect than clopidogrel. Ticagrelor also has a more rapid offset than clopidogrel by about 2 days, although the significance of this rate of offset is not that impressive, since the official labeling recommends stopping therapy 5 days before surgery.

Ticagrelor treatment is initiated with a 180-mg loading dose and continued with 90 mg twice daily. Ticagrelor should be taken with aspirin, initially 325 mg then maintained between 75-100 mg daily.

Ticagrelor has been shown to be superior to clopidogrel and improved the rate of death due to vascular causes, MI, or stroke. No difference in the rates of major bleeding was found; however, there was a higher risk of non-coronary artery bypass graft (CABG)-related bleeding with ticagrelor. Ticagrelor's superiority over clopidogrel in improving the rate of death was questionable in North America based on certain trends found in subgroup analyses, although limited evidence can be drawn from subgroup analyses. The North American data suggested that the similar efficacy seen between ticagrelor and clopidogrel may be due to prescribing practices of aspirin, which at doses greater than 100 mg may attenuate ticagrelor's antiplatelet effect.

Adverse effects seen with ticagrelor include dyspnea and ventricular pauses. The mechanism behind these adverse effects is not fully understood, but it is hypothesized that the increase in extracellular adenosine concentration caused by ticagrelor's direct binding to the P2Y<sub>12</sub> receptor may be the cause. The increased rate of dyspnea in patients taking ticagrelor has been seen in large and small studies. This raises concern that dyspnea may not be a rare adverse effect, but common.

The costs for ticagrelor, clopidogrel, and prasugrel (Effient®) are comparable currently. It is anticipated that clopidogrel will be available as a ge-

neric from multiple vendors in the next year, which may require a class review to determine the relative place of these agents from a cost-benefit perspective.

**Cellulase** is an enzyme that historically has been contained in various "digestive" products since it aids in the digestion of dietary cellulose. It has been used in the treatment of phyto-bezoars. Phyto-bezoars are bezoars [a mass entrapped in the gastrointestinal tract, usually the stomach] made up of cellulose.

A commercial source of pharmaceutical grade cellulase can no longer be obtained, although compounding pharmacies still dispense these products. Since this product is no longer commercially available for Shands at UF to purchase, it had to be deleted from the *Formulary* and designated nonformulary and not available. The use of a patient's own supply of a compounded product that cannot be verified could be problematic since the product's integrity cannot be guaranteed.

If a dietary supplement can be identified that contains sufficient cellulase, patients could use their own supply of an unopened bottle per existing policy.

**Mupirocin** is a topical antibiotic with activity against gram-positive organisms. Mupirocin ointment was first approved by the FDA in 1987; a nasal ointment was approved in 1995.

With advances in methicillin-resistant

madol, which is a weak mu-opioid agonist that prevents the reuptake of norepinephrine and serotonin. Common adverse effects associated with the use of tapentadol in clinical trials include nausea, vomiting, and drowsiness. Warnings include the risk of respiratory depression, additive CNS depression with alcohol and other opioids, and abuse potential.

The extended-release version of tapentadol has the same indication (ie, moderate to severe pain) when continuous, round-the-clock opioid analgesics are needed for extended periods. The immediate-release dosage form is given every 4 to 6 hours, while the ER dosage form is given every 12 hours.

Tapentadol products were designated nonformulary and not available. Patients cannot use their own supply of controlled substances. A different opioid should be ordered for patients admitted taking a tapentadol product. Pain medications should be titrated to response and when switching from one product to another, it may be necessary to re-titrate the appropriate dose. A pain consult could be considered. Consider using oxycodone instead of immediate-release (IR) and extended-release (ER) tapentadol using the following general guidelines for using oxycodone instead of tapentadol.

Oxycodone 5 mg every 4 to 6 hours	Tapentadol IR 50 mg every 4 to 6 hours
	Tapentadol ER 100 mg twice a day
Oxycodone 10 mg every 4 to 6 hours	Tapentadol IR 75 mg every 4 to 6 hours
	Tapentadol ER 150 mg twice a day
Oxycodone 15 mg every 4 to 6 hours	Tapentadol IR 100 mg every 4 to 6 hours
	Tapentadol ER 200 mg twice a day

*Staphylococcus aureus* (MRSA) decolonization practices within Shands at UF, the role of topical versus nasal mupirocin for decolonization of the nares was reconsidered. Outpatients are receiving topical mupirocin ointment, not nasal mupirocin ointment for decolonizing the nares. The use of topical mupirocin ointment results in an approximate \$80 per course reduction in cost. Therefore, nasal mupirocin was deleted from the *Formulary* and designated nonformulary and not available. Existing supplies of nasal mupirocin will be exhausted before it is "not available."

**Tapentadol** is a centrally acting synthetic analgesic with moderate effect at mu-opioid receptors and blocks the reuptake of norepinephrine that was approved as an immediate-release product in 2008. It has a labeled indication for the treatment of moderate to severe pain. It is a Schedule II controlled substance.

Tapentadol is most similar to tra-

For higher or lower doses of tapentadol, consult the pain service or a pharmacist. An extended-release form of oxycodone can be considered after determining the patient's response to the IR dosage form and titrating the patient's dose.

**Generic tacrolimus** will be used for all inpatients unless the patient uses their own supply of **Prograf®** from home. This decision was made after reviewing all available evidence on the interchangeability of these products.

There appeared to be no objective evidence that the use of generic tacrolimus would be problematic in the inpatient setting. However, in order to get adequate input from the services affected and to assure that all information was considered, key medical staff members who use tacrolimus were contacted to ask them to submit evidence that would prevent the interchange.

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**Formulary update, from page 3**

Some medical staff expressed concerns about the interchangeability. Their concerns were that switching would lead to more monitoring of tacrolimus levels, bioequivalency data are not applicable to the pediatric setting, multiple generics may lead to additional variability in blood levels, and loss of special programs offered with brand name drugs could affect patients.

Published data suggest that these concerns should not prohibit the inpatient use of a generic version of tacrolimus. In the inpatient setting, patients are already monitored closely because of their changing conditions. FDA states that using AB-rated generics should not justify additional levels any more than using different lots of the brand name drug. Data for bioequivalency come from healthy adult volunteers to increase the internal validity of studying the comparability of brands and generics...not the variability of drug levels in a particular patient population, which can occur with brand name drugs. Shands will not stock multiple generics. One generic will be selected. Special programs should not be affected, since these are applicable only in the outpatient setting.

Further, utilization data show that most patients are receiving generic tacrolimus in the outpatient setting. If only the brand product is used in the inpatient setting, then most patients would be switched from a generic to a brand. If switching from a generic to the brand requires additional monitoring, then additional monitoring would be necessary. However, data do not justify additional monitoring. It is not practical to stock brand and multiple generic versions of tacrolimus.

In 2009, **conventional amphotericin B (amphotericin B deoxycholate)** was restricted to use on an *Amphotericin B Order Form* in adult patients. This order form prohibited the use of traditional amphotericin B for systemic use. Only lipid amphotericin B products could be used systemically. Traditional amphotericin B was restricted to use by inhalation, bladder irrigations, and other routes (eg, intrathecal). This restriction was initiated to minimize the risks of medication error resulting in a serious overdose because of the differences in the lipid and conventional amphotericin B doses (ie, the lipid dose is much higher than the traditional dose... if a lipid dose is used for conventional amphotericin, a serious overdose occurs).

There is no evidence that conventional amphotericin B is more effective in children. Although children tolerate conventional amphotericin B better than adults do; there is experience using lipid amphotericin B products in children with good tolerance. Therefore, traditional amphotericin B can no longer be used systemically in any patients at Shands at UF.

**Unasyn**<sup>®</sup> (ampicillin/sulbactam) and **Timentin**<sup>®</sup> (ticarcillin/clavulanate) are extended-spectrum penicillins (ampicillin and ticarcillin) combined with beta-lactamase inhibitors. **Zosyn**<sup>®</sup> (piperacillin/tazobactam) has a similar spectrum of activity, including Enterobacteriaceae, Pseudomonas, and anaerobes. **Zosyn**<sup>®</sup>'s use increased this year after a **Timentin**<sup>®</sup> shortage, which has now resolved.

**Zosyn**<sup>®</sup> remains on the 72-hour restricted list and **Unasyn**<sup>®</sup> was moved to the 72-hour restricted list. **Timentin**<sup>®</sup> was moved to the prior-approval list for use in the management of infections associated with multidrug resistant gram-negative bacilli not susceptible to the formulary alternatives. **Unasyn**<sup>®</sup> now has more liberal use criteria to facilitate its uses for selected infections, like animal bites.

**Citalopram** is a commonly used selective serotonin reuptake inhibitor (SSRI). In August, the FDA notified health-

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**Formulary update, from page 4**

care professionals about the increased risk of abnormal heart rhythms associated with high doses of the antidepressant citalopram.

FDA recommends that citalopram should no longer be used at doses greater than 40 mg per day because it can cause abnormal changes in the electrical activity of the heart. Changes in the electrical activity of the heart (prolongation of the QT interval of the electrocardiogram [ECG]) can lead to an abnormal heart rhythm (including Torsade de Pointes), which can be fatal. Patients at particular risk for developing prolongation of the QT interval include those with underlying heart conditions and those who are predisposed to low levels of potassium and magnesium in the blood.

Studies did not show a benefit in the treatment of depression at doses higher than 40 mg per day. Previously, the citalopram drug label stated that certain patients may require a dose of 60 mg per day. The citalopram drug label has been revised to include the new drug dosage and usage recommendations, as well as information about the potential for QT interval prolongation and Torsade de Pointes.

Therefore, citalopram should be limited to a maximum dose of 40 mg per day. Daily dosages higher than 40-mg-per-day should occur only in patients who have had an ECG to document that the QTc is not prolonged on higher doses.

**Crizotinib** is an oral kinase inhibitor with a labeled indication for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. It is given twice a day.

Crizotinib was not added in the Formulary, but, like all new chemotherapeutic agents, it was added in the *Chemotherapy Policy*. Patients may use their own supply from home for nonformulary use. Nonformulary use of non-patient supplied crizotinib will be monitored to determine whether additional consideration is needed.

**P&T committee, from page 4**

The preceding paragraphs are slightly modified from an article, *The Hospital Formulary and the Pharmacy and Therapeutics Committee*, which appeared in the July 1970 issue of *Drugs*, which was a newsletter that preceded the *Drugs & Therapy Bulletin* at Shands at UF (SUF). These are not new concepts.

The P&T Committee has made improvements to the processes used, however. There are now 4 major ways that the P&T Committee determines what changes should be made to the *Formulary*; 1 is reactive and 3 are proactive.

Compared with most institutional P&T Committees, the SUF P&T Committee is much more proactive. Nonformulary drug use is constantly monitored. High-volume, high-risk, and high-cost nonformulary drugs are reviewed to determine whether these drugs should be readily available or their use explicitly prohibited. A nonformulary drug may be designated “not available” and Shands will not obtain this product for inpatient use. Sometimes patients may use their own supply of a “not available” drug, unless the reason it is not available is a safety concern. All new drugs and unique dosage forms are reviewed by the Formulary Subcommittee of the P&T Committee. Some new drugs do not have a role for inpatient setting and their use is prohibited. Others are important new treatments and are reviewed proactively to make sure they are available with the appropriate systems in place. Finally, the Medication Safety Committee can make recommendations to the P&T Committee regarding drug use policies and changes in the *Formulary*.

Attending physicians may request a formulary change based on existing policies. A Request for Formulary Addition form and Disclosure form must be completed. These forms are available on the portal or you may contact [hatton@shands.ufl.edu](mailto:hatton@shands.ufl.edu) for the forms.

# Drugs & Therapy

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Pegloticase	January/1,3
Phentermine	September/1,3,4
Phenytoin	February/1,3
Pilocarpine	May/1-3
Piperacillin	April/1-2
Polysaccharide-Iron Complex	February/1,3
Poractant	June/1,3
Potassium Chloride Liquid	March/1,3
Prednisolone Liquid	April/1-2
Pre-Pen	April/1-2
Prescription Trends 2010	May/1
Profiline	October/1-3
Prograf Interchange	Nov-Dec/1,3,4
Promethazine	March/1
Prothrombin Complex Concentrate	May/2,4,5
Proton-Pump Inhibitor Interchanges	October/1-2
Pyrethrum	October/1-2
Qutenza Patch	May/1-3
Rezira	July-August/1-2
Ribavirin	September/1,3
Rilpivirine	April/1-2
Rivaroxaban	October/1,3
Safyral	October/1,3
Sibutramine	March/2,4
Simvastatin	January/1,3
Sodium Chloride	September/1-3
Sodium Chloride 5% IV	April/1-2
Sodium Ferric Gluconate Complex	March/1,3
Specialty Pharmacies	February/1-3
Spinosad	April/1,3
Suboxone	July-August/2-3
Symbicort	March/1-2
Tacrolimus, Generic	July-August/1-2
Tapentadol IR & ER	Nov-Dec/1,3,4
Tdap	Nov-Dec/1,3
Tdap	January/1
Telavancin	February/1,4
Telavancin	January/1-2
Tesamorelin	October/1-3
Testosterone	February/1,3,4
Ticagrelor	May/1-3
Timentin	Nov-Dec/2-4
Tobradex	Nov-Dec/1-3
Tolvaptan	July-August/1,3
Treprostinil	June/1-2
Tripedia	February/1,4
Unasyn	Nov-Dec/2,4
Vandetanib	July-August/2-3
Vemurafenib	Nov-Dec/1,5
Ziprasidone IM	October/1,5
Zosyn	March/2,4
Zutripro	July-August/1,3
Zutripro	September/1,3