FORMULARY UPDATE
The Pharmacy and Therapeutics Committee met April 17, 2012. 3 products were added in the Formulary, and 1 drug was deleted from the Formulary. 3 products were designated nonformulary and not available. 3 interchanges were approved and criteria for use changes were approved for 2 drugs.

◆ ADDED
Albendazole (Albenza®)
Antithrombin, Recombinant (ATryn®)
Ivermectin (Stromectol®)

◆ DELETED
Antithrombin III (Thrombate III®)*
*Switch to ATryn® after current supplies are exhausted

◆ NONFORMULARY AND NOT AVAILABLE
Ivacaftor (Kalydeco®)†
†Patients should use their own supply from home
Mitomycin Kit (Mitosol®)

◆ INTERCHANGES
Aluminum hydroxide, Magnesium hydroxide, Simethicone (Generic) for Aluminum hydroxide-Magnesium hydroxide (Generic)
Famotidine (Generic) for Ranitidine (Generic)‡
‡Both oral and IV
Latanoprost (Generic) for Tafluprost (Zioptan®)§
§One drop for each drop

◆ CRITERIA-FOR-USE CHANGES
Milk of Magnesia (Generic)¶
¶Removed from all order sets

(continued on next page)

POLICIES AND PROCEDURES
Updated pharmacokinetic consult policy
Revisions to the Physician Approved Protocol for Vancomycin and Aminoglycoside Pharmacokinetic Monitoring ("Kinetics" PAP) were approved by the P&T Committee. Content changes included revised targets for aminoglycoside trough concentrations, revised vancomycin target concentrations based on the 2009 IDSA guidelines, and age clarifications for using the Schwartz equations to estimate creatinine clearance in children. Guidance was added for amikacin dosing and for dosing aminoglycoside and vancomycin in patients receiving renal replacement therapy. The option to delay obtaining vancomycin trough concentrations in stable patients until after cultures return was added. The complete policy, including revisions, can be found on the Portal.

“As resistance to antibiotics increases, optimized dosing of antimicrobials becomes even more important.”

Ordering PK Consults in the critical care and oncology areas is generally unnecessary since pharmacists automatically assist in dosing and monitoring therapy in those patients.

A protocol guides the pharmacist in providing PK Consults. The policy directs the pharmacist to order drug concentrations and make appropriate dosage adjustments. Pharmacists document PK Consults in the progress note section of EPIC and provide follow-up notes at least every 96 hours until the drug or consult is discontinued.

Individualized dosing of aminoglycosides using pharmacokinetic calculations has been shown to achieve desired blood concentrations (peaks and troughs) more rapidly than other methods. The number of drug concentrations ordered may be reduced as well. As resistance to antibiotics increases, optimized dosing of antimicrobials becomes even more important. Only trained pharmacists at Shands at UF provide PK Consults and quality assurance is performed.

Revisions to this policy were reviewed by pediatric and adult clinical pharmacists and reflected needed practice changes based on the conversion to EPIC in May 2011. Changes were also reviewed and endorsed by the Anti-Infective Subcommittee and the Division of Nephrology of the Department of Medicine.

INSIDE THIS ISSUE
◆ Holding hypotensive drugs?
◆ Anticoagulation management
◆ Glycemic control in the hospital
Nicardipine (Generic)**

**Pregnancy is a reasonable criterion for avoiding nitropresside

Albendazole and ivermectin are rarely used anti-infective agents used for parasites that were added in the Formulary. These agents are occasionally used for roundworm (strongyloidiasis) and other infections. Because they are anti-infectives, they have been high-priority nonformulary agents despite their infrequent use. They were evaluated proactively to determine their formulary status and whether they should be used.

Albendazole is an anthelmintic agent with labeled indications for cysticercosis, neurocysticercosis, and hydatid cyst disease. Off-label use for endoparasitic infections, including strongyloidiasis and giardiasis, is “common.” Other off-label uses include trichuriasis, ascariasis, enterobiasis, hookworm infection, capillariasis, pediculosis, microsporidiosis, taeniasis, trichostrongyliasis, and secondary treatment for cutaneous larva migrans. Albendazole offers an alternative to mebendazole, which was deleted from the Formulary in November 2011 because it is no longer marketed.

Albendazole has been shown to be effective for a wide variety of indications including cysticercosis, neurocysticercosis, hydatid cyst disease, ascariasis, hookworm, pediculosis, and giardiasis infection. Albendazole has been shown to be less effective than ivermectin in the treatment of strongyloidiasis. In a review of the efficacy of albendazole, 19 studies of the treatment of strongyloidiasis with albendazole were evaluated. At 14-21 days after initial treatment, cure rates with albendazole were 62.2%. Ivermectin had a cure rate of 97% in one study, while albendazole had a cure rate of 23.3%. In another study comparing ivermectin and albendazole for the treatment of strongyloidiasis, ivermectin outperformed albendazole and achieved cure rates of 83% versus 38%.

Albendazole was added for other uses. For pediculosis, studies have shown that albendazole has a cure rate of approximately 80%. A study comparing albendazole to metronidazole in the treatment of Giardia duodenalis, albendazole was shown to be as effective as metronidazole with fewer adverse effects.

The only contraindication to the use of albendazole is hypersensitivity to any component of the product or to any agent in the benzimidazole class. Common adverse drug reactions in patients being treated for hydatid disease are usually mild and reversible and include abnormal liver function tests, abdominal pain, nausea, vomiting, reversible alopecia, and fever. Overall, albendazole has few adverse effects and is very well tolerated.

The acquisition cost of this agent is reasonable. A typical course of treatment of strongyloidiasis would cost about $15.00.

Ivermectin is an antiparasitic agent with a labeled indication for the treatment of strongyloidiasis and onchocerciasis caused by Strongyloides stercoralis and Onchocerca volvulus. It has many off-label uses including scabies, pediculosis, filariasis, cutaneous larva currens, and cutaneous larva migrans.

Efficacy data are mostly confined to the results of a limited number of small, prospective trials. As previously described, ivermectin has the best cure rates for strongyloidiasis.

Ivermectin is contraindicated in patients with a history of hypersensitivity to any component of the product. Most of the adverse events for this medication are mild and temporary. In clinical trials with patients being treated for strongyloidiasis, the most common adverse drug reactions included elevation of liver function tests (AST/ALT), decreased leukocytes, dizziness, itching, asthma, fatigue, abdominal pain, nausea, vomiting, diarrhea, constipation, anorexia, somnolence, tremor, and vertigo. In post-marketing studies, the following adverse drug reactions have been reported: worsening of bronchial asthma, conjunctival hemorrhage, toxic epidermal necrolysis, Stevens-Johnson syndrome, seizures, hepatitis, and elevation of bilirubin.

The acquisition cost of this agent is reasonable. For many indications, ivermectin is given as a 1-time dose. The cost of a treatment dose of ivermectin for a 70-kg man with strongyloidiasis would be about $20.00.

ATryn® was added in the Formulary and will replace Thrombate III® as the antithrombin product available at Shands at UF once supplies have been exhausted. Antithrombin III is a plasma factor necessary for heparin to exert its anticoagulant activity. It is a natural anticoagulant synthesized in the liver and plays a major role in the regulation of hemostasis.

Antithrombin III has a labeled indication for the prevention of perioperative and peri-partum thromboembolic events in patients with hereditary antithrombin deficiency. It does not have a labeled indication for treatment of thromboembolic events in patients with antithrombin deficiency. It is used off-label in some patients at Shands at UF with heparin resistance undergoing cardiopulmonary bypass.

Thrombate III® is antithrombin III pooled from human plasma and was added in the Formulary in November 2009. At that time, ATryn®, which is the recombinant form of antithrombin, was designated nonformulary and not available because it was more expensive and offered no advantage.

Thrombate III® is now more expensive and its supply is more problematic than with ATryn®. Therefore ATryn® replaced Thrombate III® based on cost and supply issues, not therapeutic superiority. The switch will be made once supplies of Thrombate III® have been exhausted.

Ivacaftor is a novel drug used in the treatment of cystic fibrosis (CF). In CF, an autosomal recessive disorder, cellular ion and fluid transport does not function properly, leading to viscous secretions, especially in the lungs. Ivacaftor works by potentiating the effects of the CF Transmembrane Conductance Regulator (CFTR) in patients who have a G551D mutation of the CFTR allele, thus treating the source rather than symptoms of disease. This facilitates movement of chloride ions across cell membranes, and leads to increased fluid movement in the lungs. Increased fluid decreases sputum viscosity in the lungs and improves lung function.

Ivacaftor is only effective in patients who have a G551D mutation on the CFTR allele. It is not effective in other types of mutations, including the F508del mutation, the most common type. The G551D mutation only (continued on next page)
Formulary update, from page 2
makes up a small patient population of CF patients, with studies citing incidence rates between 1.6% and 5%. Approximately 1,000 patients in the United States are affected by this mutation and are thus candidates to receive ivacaftor. Few patients at UHF&Shands are known to have this mutation currently. New patients are routinely screened for this mutation.

Ivacaftor is available as a 150-mg tablet, administered twice daily. While no long-term studies have established efficacy for periods longer than 48 weeks, it is intended that ivacaftor be given as lifelong maintenance therapy.

Phase II and III trials showed benefit with ivacaftor in absolute change from baseline to week 24 in percent of predicted FEV1. Benefit with ivacaftor in clinical outcomes, including pulmonary exacerbation and hospitalization rates were seen at 24 and 48 weeks. Subjectively reported disease burden improved with ivacaftor by approximately 6 points on a 100-point scale over 48 weeks. The most recent trial supporting FDA approval of ivacaftor is only published in the official labeling.

The adverse event profile of ivacaftor includes headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, dizziness, and elevated liver enzymes.

Ivacaftor is extremely expensive, with wholesale acquisition costs of $408.33 per tablet. Therefore, an average 7-day treatment course would cost approximately $5,700 to acquire the drug, and a 30-day treatment course would cost approximately $25,000 (ie, about $300,000 per year). Continuation of therapy after inpatient initiation of ivacaftor may be difficult financially and should be considered in decisions to initiate treatment.

Because of the extremely small treatable patient population, its chronic prophylactic role, and high acquisition cost, ivacaftor was designated nonformulary and not available for inpatient use. Patients who are hospitalized already taking ivacaftor will take their own supply from home.

Mitosol® is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery. It is intended for topical application to the surgical site of glaucoma filtration surgery. The Department of Ophthalmology stated that mitomycin is used for this purpose, but at a concentration different from that provided by Mitosol®. Therefore, Mitosol® was designated nonformulary and not available.

Antacid suspensions containing aluminum and magnesium hydroxide have been used for many years to neutralize stomach acid rapidly. When used in combination, the most common adverse effects associated with each cation (aluminum = constipation and magnesium = diarrhea) offset each other, theoretically. However, diarrhea is still the more common adverse effect.

Original Maalox® liquid was the brand product most often associated with the combination of aluminum and magnesium hydroxide. There have been various generic equivalents for many years.

In the hospital setting, liquid antacid is commonly dispensed in pre-measured cups that provide a unit dose. This is convenient because liquid antacids are frequently ordered for “as needed” (PRN) use.

Recently, aluminum-magnesium hydroxide suspensions have been replaced by aluminum-magnesium hydroxide combinations with simethicone by most vendors. For example, Maalox® Antacid liquid now contains simethicone with aluminum and magnesium hydroxide. Few vendors market aluminum-magnesium hydroxide alone without simethicone. Pre-measured cups of aluminum-magnesium hydroxide have been difficult to obtain.

Pre-measured cups containing aluminum hydroxide, magnesium hydroxide, and simethicone are more widely available. Simethicone is an anti-foaming agent that is promoted to relieve “gas.” Dimethicone is a similar “gas-relief” ingredient that is often found in nonprescription antacid suspensions. Simethicone is not absorbed and is considered safe.

Based on availability of unit-dose cups of antacid liquids, the P&T Committee approved the interchangeability of aluminum-magnesium hydroxide suspensions [only] with suspensions also containing simethicone.

Famotidine and ranitidine replaced famotidine in the Formulary. The P&T Committee has long considered H2-receptor blockers therapeutically equivalent. Whenever possible, the Committee has tried to keep the injectable and oral H2-blocker the same to facilitate IV-to-PO interchanges.

Recently, a shortage of ranitidine required a temporary change to famotidine as the injectable H2-blocker in the Formulary. It is anticipated that this shortage will not be resolved for an extended period and a financial analysis suggests that a switch to famotidine would decrease pharmaceutical expenditures.

Interchanges will be based on previously approved therapeutically equivalent dosages.

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<tr>
<th>Famotidine Dosage</th>
<th>Ranitidine Dosage</th>
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<tr>
<td>20 mg IV every 12 hours</td>
<td>50 mg IV every 8 hours</td>
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<tr>
<td>20 mg tablets twice a day</td>
<td>150 mg tablets twice a day</td>
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<tr>
<td>30 mg oral liquid twice a day</td>
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Tafoprost is a prostaglandin analog with a labeled indication for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Pharmacologic treatment of open-angle glaucoma includes topical medications that increase aqueous outflow (prostaglandins, alpha-adrenergic agonists, cholinergic agonists) or decrease aqueous production (alpha-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors). Topical prostaglandins are generally considered first-line therapy as most meta-analyses have found prostaglandins to be more effective than other agents have.

Latanoprost, another ophthalmic prostaglandin, was listed in the Formulary in September 2002. In May 2008, bimatoprost, travoprost, and unoprostone were designated nonformulary and not available and interchanged (same dosage, usually 1 drop per day) to latanoprost. Tafluprost will be interchanged to latanoprost at an equivalent dosage (ie, 1 drop of latanoprost for 1 drop of tafluprost), consistent with the interchanges for bimatoprost, travoprost, and unoprostone. Patients may continue to use their own supply of tafluprost, if ordered by their prescriber.

Milk of magnesia (MOM) in ready-to-use, unit-dose cups has been discontinued. Milk of magnesia is an (continued on next page)
Nicardipine is a dihydropyridine calcium-channel blocking agent used for the treatment of vascular disorders such as chronic stable angina, hypertension, and Raynaud’s phenomenon. It is administered as the intravenous formulation when oral therapy is not feasible or desirable.

Nicardipine’s advantages include rapid onset and offset, lack of accumulation of toxic metabolites (as with sodium nitroprusside), and lack of increase in intracranial pressure. Disadvantages include cost, contraindication in aortic stenosis, and potential for interaction with anesthetics.

A review of the literature regarding nicardipine’s use in pre-eclampsia determined that the current criteria for use could be expanded for this condition due to differences in blood pressure goals, desired time to therapeutic effect, differences in usual first-line therapeutic agents, and potential toxicity from sodium nitroprusside to mother and fetus.

In June 2011, the P&T Committee approved criteria for nicardipine use to include continuous infusion for blood pressure management and when blood pressure control fails with both labetalol and nitroprusside or when patients have failed blood pressure control with one and have a contraindication to another. Since criteria for use currently adequately reflect findings of this review regarding indications, pregnancy is considered a rationale for skipping sodium nitroprusside and using nicardipine in the appropriate setting to assure proper monitoring (eg, ICU). Hydralazine and labetalol are preferred, however.

### Oral Hypotensive Drugs

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<td>Carvedilol</td>
<td>Propanolol</td>
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<td>Labetalol</td>
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<th>Angiotensin Converting Enzyme and Angiotensin Receptor Blockers</th>
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<tr>
<td>Captoprill</td>
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<td>Enalapril</td>
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<td>Lisinopril</td>
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<th>Calcium Channel Blockers – Nondihydropyridines</th>
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<td>Hydralazine</td>
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<td>Isosorbide</td>
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### Anticoagulation Management at Shands at UF

Anticoagulants are frequently used in hospitalized patients and, nearly just as frequently, cause a multitude of problems. Therefore, the Institute for Safe Medication Practices has included these agents on its list of high-alert medications. High-alert medications are those that are most frequently associated with patient harm when a medication error occurs. Additionally, the Institute for Healthcare Improvement has targeted anticoagulants in its Protecting 5 Million Lives from Harm campaign.

The primary goals of the anticoagulant management program at Shands at UF are to maximize the safety and efficacy of these compounds in patients receiving them while under our care and to comply with Joint National Patient Safety Goals for Anticoagulation. The purpose of this article is to briefly review the program (continued on next page)
Anticoagulation management, from page 4

at Shands at UF, including some of its components, as well as provide sources of greater detail for those interested.

In order to meet the goals described above, the program is divided into its components: 1) education; 2) policies and procedures, and; 3) clinical monitoring. This article is an example of the educational component. There have been numerous previous articles covering topics such as monitoring unfractionated heparin and warfarin and individualized dosing of warfarin. Future topics include comparisons of efficacy and safety of warfarin versus dabigatran and warfarin versus rivaroxaban. Suggestions for additional topics should be sent to Dr. Larry Lopez at lopez@cop.ufl.edu.

Detailed policies and procedures of this program are available for review on the Pharmacy Services portion of the Shands at UF Portal. Some policies are subtle and many physicians may have already encountered them without realizing it. For example, the only dosage forms of warfarin that are used in this institution are those unit-dose forms available from a manufacturer. Similarly, only manufacturer produced pre-filled syringes are provided for any of the low-molecular weight heparins except for special cases where a dose from a multiple-dose vial with be prepared before it is dispensed by the Pharmacy Department.

“...the program is divided into its components: 1) education; 2) policies and procedures, and; 3) clinical monitoring.”

Other policies are more overt and may actually require an active intervention by a pharmacist. For example, a baseline INR must be available before the first dose of a new order for warfarin will be dispensed. If a baseline INR is not available, a pharmacist is authorized to order an INR before providing the warfarin dose. Additionally, warfarin will not be dispensed for any patient with an INR of greater than 4. Count on receiving a call from a pharmacist should this ever occur with one of your patients.

Finally, recommendations for clinical monitoring of anticoagulants are approved by the P&T Committee and are available on the Pharmacy Department web page located on the Shands at UF Portal. Laboratory monitoring of unfractionated heparin and low molecular weight heparins, warfarin, and argatroban is best accomplished with appropriately timed anti-Xa levels, INR, or aPTT, respectively. Guidelines for interpretation of these results and frequency of monitoring are included in the same document, which is only 3 pages in length and well worth the minimal amount of time needed to review.

Anticoagulant therapy has been and will continue to be both very beneficial for our patients but also the type of therapy that demands considerable clinical vigilance from all involved in their care. The Anticoagulation Management Program at Shands at UF is designed to assist all health care professionals in the most effective use of anticoagulants in our patients but also to use these same medications in as safe a manner as possible. All are invited to review any one or all parts of this program, but are reminded that the program is neither intended to nor should it substitute for continuous and aggressive individual clinical vigilance.  

By Larry Lopez, PharmD

What’s all the hype...about hyperglycemia? Glycemic control in hospitalized patients.

Hyperglycemia in hospitalized patients is associated with adverse outcomes, increased length of stay, and increased healthcare expenditures. It is estimated that as many as one-third of patients will experience hyperglycemia during their hospitalization. Hyperglycemia is defined as any blood glucose value greater than 140 mg/dL. Blood glucose values that remain persistently elevated may necessitate treatment. Obtaining a hemoglobin A1c (A1C) can help determine the source of hyperglycemia and whether it is diabetes-related. An A1C value of greater than 7% most likely suggests that diabetes preceded the current hospitalization.

Not surprisingly, uncontrolled blood glucose can often be attributed to poor inpatient management in patients with existing diabetes through the sole use of “sliding-scale insulin.” Other causes include stress, medications, and fear of causing unnecessary hypoglycemia. Achieving blood glucose control should be a top priority for hospitals and front-line staff to improve short and long-term patient outcomes. The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) have recently published a consensus statement on inpatient glycemic control. Recommended goal blood glucose ranges are specified for non-critically ill patients (pre-meal blood glucose less than 140 mg/dL and random blood glucose less than 180 mg/dL) and critically ill patients (140 to 180 mg/dL), as are exceptions to each. The ADA/AACE guidelines serve as a great source of information and clinical guidance based on patient level of care and dietary intake.

One of the biggest barriers observed when attempting to improve blood glucose control is the fear of causing hypoglycemia as a result of an intervention. Hospitalized patients exhibiting uncontrolled blood glucose may be acutely ill and have an erratic caloric intake creating a daunting and challenging prescribing environment for practitioners. One of the easiest ways to avoid hypoglycemia is to hold all oral antihyperglycemic drugs while the patient remains in the hospital. A patient who remains on the oral hypoglycemic drugs they take at home can place the patient at risk for hypoglycemia in addition to other well-known adverse events. For example, metformin should not be used inpatient if there is a possibility for concurrent administration of iodinated contrast, or in patients with renal dysfunction, circulatory compromise, and/or hypoxemia due to the increased risk of lactic acidosis. Sulfonylureas and meglitinide drugs have the potential to cause hypoglycemia in patients with inconsistent caloric intake. Thiazolidinediones can cause fluid retention when used in combination with insulin therapy. Parenteral glucagon-like peptide-1 receptor agonists and amylin agonists may cause pronounced nausea in acutely ill patients.

So, the question remains...if we hold oral antihyperglycemic drugs at the time of admission, what do we use to manage patients at Shands at UF? The overwhelming recommendation is insulin, insulin, and more insulin... in (continued on page 6)
Glycemic control in the hospital, from page 5

most clinical situations. When admitted to the hospital, for the reasons listed above, insulin therapy is the ideal agent to manage blood glucose. Outside of an intensive care unit (ICU) setting, scheduled subcutaneous insulin is the preferred method for achieving and maintaining blood glucose control and should consist of 3 key components: a basal, a nutritional, and a correctional insulin. This type of glycemic control provides greater flexibility to adapt to erratic inpatient caloric intake or the chance that a patient may be ordered “nothing by mouth” (NPO) for a portion of their stay. The flexibility is found within the nutritional or bolus insulin therapy, so if a patient were to skip a meal the nutritional insulin, which is given just prior to meals, is withheld. The basal insulin in this case may be continued and this is because basal insulin mimics our own physiologic release of insulin over the course of a day and should not be affected by erratic caloric intake patients often encounter.

Too often, we see the sole use of “sliding scale insulin,” which is an unreliable and often dangerous method to lower blood glucose. It is a reactive instead of proactive practice that carries the potential to place patients at risk for hypoglycemia.1

In an ICU setting, continuous insulin infusions are often used to allow for rapid dose adjustments for variations in patient status. Once a patient is stable on a continuous insulin infusion and future fluctuations are not likely to occur, patients may be safely transitioned to scheduled subcutaneous insulin therapy as discussed above. At Shands at UF, continuous insulin infusions are restricted to ICUs and intermediate care settings. It is important to assess previous requirements when transitioning from one level of care to the next to ensure continuity of care.

Guidance on when to use what type of insulin, initial dosing, titration frequency, and recommendations on how to transition from a continuous insulin infusion can be found in the references below.2,4 An understanding of the “basal-bolus” method using the 3 key components of insulin therapy can help to achieve positive patient outcomes while providing the needed flexibility for hospitalized patients. Although insulin therapy is recommended for inpatient glycemic control, most patients will not require insulin therapy upon discharge. As mentioned previously, a patient’s A1C is a good marker of controlled blood glucose and whether the patient can be transitioned home on their prior-to-admission antihyperglycemic drugs. If an A1C is suboptimal, indicating poorly controlled blood glucose before admission, intensification of outpatient therapy is then warranted.

By Jessica M. Cope, PharmD

REFERENCES