OUR LADY OF THE LAKE RMC

InPharmation

The official publication of the Pharmacy Department

Volume , Issue

Hyperlipidemia Guideline Update

In a departure from recommendations by the American Heart Association (AHA), the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) have issued new lipid management guidelines that recommend LDL target goals based on risk for cardiovascular events. These two endocrine groups bring back LDL-cholesterol "targets" and are the first ever to include a new "extreme-risk" category of patients for whom an LDL-cholesterol level of less than 55 mg/dL is now advised.

The AACE and ACE divide patients into five definitive atherosclerotic cardiovascular disease (ASCVD) risk categories (Table 1) in their newest guidelines for the management of patients with hyperlipidemia. The extreme -risk group includes patients who still have cardiovascular dysfunction after achieving an LDL level less than 70. They recommend a new goal of less than 50. This group's chance of having a cardiovascular event is 10%-14% per year, climbing to 50% at 5 years. These patients may require combination therapy—a statin and a PCSK9 inhibitor—to get to the new stringent goal of 55 mg/dL.

Very high-risk patients include the group of people we commonly see in the hospital. These are described as the patients who have been hospitalized recently for an ACS event, have diabetes, or a 10-year risk greater than 20%. The rest of the categories comprise of patients who have risk factors such as cigarette smoking, hypertension, low HDL, family history of coronary artery disease, chronic renal disease stage 3 or 4, evidence of coronary artery calcification, and/or age (men ≥ 45 and women ≥ 55 years). Subtract 1 risk factor if the person has high HDL.

Although statins are relatively cost-effective, extended statin therapy comes with risks. Statins carry the risk of rhabdomyolysis and muscle dystrophy, and prolonged use of high-intensity statins may exacerbate these effects. According to the AHA guidelines, the benefit of reduced cardiovascular risk seems to outweigh these risks.

The authors believe that the LDL targets, like hemoglobin A1c and blood pressure goals, serve as useful incentives for both clinicians and patients, but they are not entirely adopted. With such strict treatment goals, what does that mean for patient cost? These extremely lowered goals will lead to either combination therapy or prolonged treatment while increasing the possibility of side effects.

These factors contribute greatly to the cost of therapy in patients who have elevated levels. Combination therapy with Zetia is an option that reduces levels greater than monotherapy; however, this may not always be an affordable alternative for patients.

Although, the 2013 AHA guidelines did away with target goals, the AACE/ACE guidelines never really did. It is important to highlight that these changes are only recommendations by the endocrinologists and are not a definitive target to be used in daily practice.

Inside this issue:

Risk Category	Criteria	LDL Treatment Goal (mg/dL)
Extreme risk	Progressive ASCVD in patients after achieving LDL < 70, established clinical cardiovascular disease in patients with diabetes or CKD stages III/IV	< 55 mg/dL
Very high risk	Established or recent hospitalization for ACS or vascular disease, 10-year risk > 20%, diabetes or CKD stages III/IV with one or more risk factors	< 70
High risk	Two or more risk factors and ASCVD 10-year risk 10-20%, diabetes or CKD stages III/IV with no other risk factors	< 100
Moderate risk	Less than two risk factors, ASCVD 10-year-risk < 10%	< 100
Low risk	No risk factors	< 130

Table 1: AACE and ACE risk categories for determining LDL-cholesterol target goals in the treatment of hyperlipidemia.

Formulary Changes

Entresto, a combination of neprilysin inhibitor, sacubitril, and angiotensin II receptor blocker, valsartan, is used to decrease mortality in patients with NYHA class II-IV heart failure. Approved in 2015, this drug has previously had restrictions for use at Our Lady of the Lake Regional Medical Center. However, recently, Entresto has received a formulary status change. Entresto will remain on the formulary and can be prescribed openly without restrictions. When pharmacists receive this order for verification, it will include a note in the order instructions that reads: "Concomitant use of an ACE inhibitor is contraindicated; allow a 36 hour washout period when switching from or to an ACE inhibitor." This order instruction is consistent with the instruction included in the package insert provided by the Novartis Pharmaceutical Company. Our Lady of the Lake will continue to carry all strengths of this medication: 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg.

Patient Safety Corner

ISMP Safety Practice Guidelines

This patient safety corner is brought to you by the 2016-2017 ISMP Targeted Medication Safety Best Practices for Hospitals

Best Practice 11:
Compounding Sterile Preparations

When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient **prior** to its addition to the final container.

- Eliminating the use of the "syringe pull-back method" and checking ingredients rather than labels can decrease risk
- Perform this verification practice in all locations where CSPs are made, except in emergencies
- At minimum, these verifications should be performed on high-alert medications, pediatric and neonatal preparations, bulk containers, and products with high-risk routes of administration (intrathecal, epidural, and etc.)
- Use of technology such as IV workflow software and barcode scanning verification. Ensure this software is always up-to-date and maintained

Rationale

ISMP continually receives reports of errors that result in serious harm due to a failed check system, especially when using the "syringe pull-back method". Using this method does not allow for proper verification because these errors may not be detected if the syringe is not partnered with the correct drug or the pulled –back syringe does not accurately reflect what was previously drawn up and placed into its final container.

From 2004-2011, there have been 9 deaths reported due to wrong concentration/strength or wrong product/diluent. These deaths could have been avoided easily if preproduction checks were performed to ensure that right drugs at the right concentrations were properly compounded.

ISMP has warned against the use of this method since 2010. High-alert medications and pediatric medications are two examples of medications that should especially avoid this method.

Regulatory

Recent FDA Approvals

- Enasidenib (Idhifa) was approved in August 2017 for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an IDH2 mutation.
- The combination of allopurinol and lesinurad (Duzallo) was approved in August 2017 for the treatment of hyperuricemia in patients with uncontrolled gout.
- The combination of meropenem and vaborbactam (Vabomere) was approved in August 2017 for the treatment of complicated UTI caused by various drug-resistant strains bacteria.
- Neratinib (Nerlynx) was approved in July 2017 for the extended adjuvant treatment of patients with early-stage HER2 overexpressed breast cancer.
- Delafloxacin (Baxdela) was approved in June 2017 for the treatment of acute bacterial skin and skin structure infections.
- Betrixaban (Bevyxxa) was approved in June 2017 for VTE prophylaxis in hospitalized adults at risk for thromboembolic complications due to severely restricted mobility.

FDA Med Safety Alert

- Vancomycin HCl solution for injection (manufactured by Hospira, Inc.) has been issued a medication safety alert for possible containment of particulate matter.

Health Alert Updates

- The CDC has issued a health alert due to the increase in case reports of cyclosporiasis. This alert recommends that healthcare providers consider a diagnosis of cyclosporiasis in patients with prolonged or remitting-relapsing diarrhea. Several stool samples may be required for testing and all diagnosed cases should be reported to the local health department.
- Patients receiving eculizumab (Soliris) have a 1,000 to 2,000-fold greater risk for developing invasive meningococcal disease compared to people not using Soliris. Because of this, the drug has been issued a black box warning for increased risk of meningococcal disease and vaccination should be considered for these patients. If meningococcal vaccination is deemed appropriate, it is recommended to administer the vaccine at least two weeks prior to initiation of Soliris.

Reminders

Current drug shortages include:

- Sodium bicarbonate vials and syringes
- Epinephrine 1 mg/ml 30 mL vials
- Pantoprazole 40 mg injection
- Hydromorphone 2 mg/mL injection
- Morphine 2 mg and 4 mg carpujects
- Fentanyl 50 mg/mL 5 mL vials
- Sodium and potassium acetate
- Dextrose 50% 50 mL syringes
- Levophed ampules and vials
- Bicillin L-A 1.2 and 2.4 million units
- Bicillin CR 1.2 million units

The last day to complete the Healthy Lives screening is September 30th.

The IV room was reopened on September 7th and will return to full use for the preparation of IV solutions and other medications. Blue shoe covers are no longer required to enter the workroom, but traffic in this area should still be limited.

The IV push program has recently been expanded to all units of the hospital. Refer to the protocol to determine which medications can be automatically changed from IVPB to IV push.

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