Label changes coming to hydrochlorothiazide to warn about non-melanoma risk
In late August, FDA approved labeling changes on hydrochlorothiazide (HCTZ) to inform clinicians and patients about a small risk of developing non-melanoma skin cancer—basal cell skin cancer or squamous cell skin cancer—associated with the use of HCTZ. At the same time, FDA is encouraging patients to protect their skin from the sun.

Specifically, the labeling changes will include the following:

- Adverse Reactions, Postmarketing Experience: Information has been added about an increased risk of non-melanoma skin cancer associated with HCTZ.

- Patient Counseling Information: Information has been added instructing patients to protect their skin from the sun and undergo regular skin cancer screenings.

FDA based the changes on recent evidence, specifically an FDA Sentinel Initiative study that found an increased risk for squamous cell carcinoma in patients taking HCTZ. In the overall study population, the risk was one additional case per 16,000 patients per year.

In a statement, FDA said the “increased risk of developing non-melanoma skin cancer while taking HCTZ, a drug associated with photosensitivity (increased sensitivity to sunlight), is small.”

In addition, FDA noted that the treatment for non-melanoma skin cancer is typically successful, but the risks of uncontrolled blood pressure can be severe and include life-threatening heart attacks or stroke.

“Given this information, patients should continue to use HCTZ and take protective skin care measures to reduce their risk of non-melanoma skin cancer, unless directed otherwise from their health care provider,” the agency stated.

HCTZ is one of the most commonly prescribed drugs in the United States, with an estimated 10 million patients using the drug each year for conditions such as hypertension and diabetes.

Oncologists prescribing fewer opioids worries researchers
The opioid epidemic has prompted several legislative and regulatory efforts aimed at inappropriate opioid prescribing. Some experts wonder, however, whether oncology patients are getting their needs met amid the sea change.

A new study, published online in August in the *Journal of the National Cancer Institute*, looked at whether these efforts to curb opioid prescribing have
affected prescribing among oncologists, whose patients often require opioids for symptom management.

The research team, led by Vikram Jairam, MD, from Yale University School of Medicine, found that from 2013 to 2017, opioid prescribing in the United States significantly decreased nationwide among oncologists and non-oncologists. The rate of decline was 20.7% for oncologists and 22.8% among non-oncologist physicians.

“Given similar declines in opioid prescribing among oncologists and non-oncologists, there is concern that opioid prescribing guidelines intended for the non-cancer population are being applied inappropriately to patients with cancer and survivors,” the authors noted in the study.

The researchers also found that during the 5-year study period, 43 states experienced a decrease in opioid prescribing among oncologists. And in five states, opioid prescribing decreased more among oncologists than non-oncologist physicians. For palliative care providers, opioid prescribing increased by 15.3%, according to the research.

The findings were based on Medicare prescription claims data, specifically CMS’s Part D prescriber dataset.

New CMS rule increases coverage of new treatments

On September 2, CMS issued the FY2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) final rule, which is intended to increase access to potentially life-saving diagnostics and therapies for hospitalized Medicare patients. The changes will affect approximately 3,200 acute care hospitals and approximately 360 long-term care hospitals.

The new CMS rule creates a Medicare Severity Diagnostic Related Group that provides a predictable payment to help adequately compensate hospitals for administering chimeric antigen receptor (CAR) T-cell therapies, which use a patient’s genetically modified immune cells to treat specific types of cancer.

The rule also includes 24 new technology add-on payments (NTAP), additional payments to hospitals for cases involving eligible new and relatively high-cost technologies via alternative streamlined pathways established last year that allow FDA breakthrough devices and qualified infectious disease products to qualify for NTAPs while real-world evidence is emerging.

CMS is also expanding the add-on payment alternative pathway for antimicrobial products under a program that encourages the development of safe and effective medications to address unmet needs of patients with serious bacterial and fungal infections.

Finally, CMS is taking steps to ensure that the Medicare FFS program adopts pricing strategies based on real-world market forces. Medicare generally pays hospitals a rate that is weighted by the relative cost of providing certain services based on a patient’s diagnosis. However, these weights are based largely on the charges that hospitals report to the federal government, which are often different from the actual rates insurance companies pay. Hospitals are already required to report these negotiated rates, and CMS is now finalizing a requirement for hospitals to report the median rate negotiated with Medicare Advantage Organizations for inpatient services, which will be used instead of the charge-based data. CMS will begin to collect this data in 2021 and will use it in the methodology for calculating inpatient hospital payments beginning in 2024.

For a fact sheet on the final rule (CMS-1735-F), visit the CMS newsroom at www.cms.gov.

Low-dose morphine may have a positive effect in patients with COPD

Use of regular, low-dose, oral sustained-release morphine for 4 weeks may have a positive effect on assessment test scores in patients with COPD who had moderate to severe breathlessness without causing respiratory adverse effects, according to a study published online on August 17 in JAMA Internal Medicine.

In the randomized clinical trial, researchers at Maastricht University in Horn, Netherlands, and the Ludwig Boltzmann Institute for Lung Health in Vienna, Austria, assessed 111 patients with COPD. They randomly assigned patients to either 10 mg of regular, oral sustained-release morphine or placebo twice daily for 4 weeks, with a possible increase to three times daily after 1 or 2 weeks. Participants had a mean age of 65.4 years, were 54% male, and were recruited in a pulmonary rehabilitation center and two general hospitals after completion of a pulmonary rehabilitation program. The COPD assessment test score was 2.18 points lower and PaCO2 1.19 mm Hg higher in the morphine group. Breathlessness remained unchanged. Five out of 54 participants in the morphine group and 1 out of 57 participants in the placebo group withdrew from the trial because of adverse effects. No morphine-related hospital admissions or deaths occurred.