### FDA Update

**Over-the-counter test for flu, COVID-19 authorized**

By Mollie Frost

#### Recalls

A class I recall of certain CADD infusion system administration sets and medication cassette reservoirs by Smiths Medical due to two potential issues. The first issue, tubing occlusion, may result in underdelivery or nondelivery of medication, despite the pump displaying that the infusion is running properly. The second issue, false “no disposable attached” alarms, may prevent pump use. There have been 1,571 incidents, 14 injuries, and two deaths related to the tubing occlusion issue and 9,101 incidents, 11 injuries, and no deaths related to the false alarm issue. The recall includes about 20 million devices distributed since June 15, 2018.

A class I recall of Nuclear Medicine 600/800 Series Systems by GE HealthCare due to an issue with two mechanisms that prevent uncontrolled detector movement. If the ball screw fails and the safety key is missing, the 3,121-pound detector could fall, potentially crushing or trapping a patient. The company internally identified the issue, and no related complaints, injuries, or deaths have been reported. The recall includes 688 devices distributed from April 11, 2018, to Dec. 16, 2022.

A recall of 27 lots of levotyrosine sodium oral solution (TiroSINT-SOL) by IBSA Pharma Inc. due to a company analysis showing a slight decrease below 95% of its labeled amount of levotyrosine sodium (T4) for some lots. The recall does not apply to levotyrosine sodium capsules (TiroSINT). No related adverse events have been reported.

A recall of all lots of Artificial Tears Lubricant Eye Drops by Global Pharma Healthcare, distributed by EzriCare LLC and DeSams Pharma, due to potential microbial contamination. The CDC alerted the FDA to an investigation of a multistate cluster of Verona integron-mediated metallo-β-lactamase and Guiana-extended spectrumb-β-lactamase-producing carbapenem-resistant Pseudomonas aeruginosa infections possibly associated with the use of these products. There have been 55 reports of adverse events, including eye infections, permanent loss of vision, and a death with a bloodstream infection. The FDA also placed the manufacturer on import alert for providing an inadequate response to a records request and current good manufacturing practice violations.

A recall of all lots of Alcohol Antiseptic 80% Alcohol Solution by nanoMaterials Discovery Corporation branded as “Snowy Range Blue” because certain batches may exceed FDA limits for methanol. No related adverse events have been reported. Affected products were sold nationwide to distributors. Sales of the product were discontinued in the fourth quarter of 2021.

#### Miscellaneous

A letter to clinicians about the risk of early structural valve deterioration with Abbott Trifecta valves, including the Trifecta Valve and the Trifecta Valve with Glide Technology (Trifecta GT). Information from published literature has shown a higher cumulative incidence of early (five years or fewer) structural valve deterioration for these valves compared to other commercially available surgical bioprosthetic valves. The FDA is working with the manufacturer to further evaluate the issue and develop additional patient management strategies, if needed.

**COVID-19 updates**

An emergency use authorization (EUA) for the first over-the-counter at-home diagnostic test that can differentiate and detect influenza A and B and SARS-CoV-2. The Lucira COVID-19 & Flu Test is a single-use at-home test kit that provides results from self-collected nasal swab samples in roughly 30 minutes. Patients can purchase the test without a prescription and perform it using nasal swab samples self-collected by patients ages 14 years and older or collected by an adult for children 2 years of age or older. In symptomatic patients, the test correctly identified 99.3% of negative and 90.1% of positive influenza A samples, 100% of negative and 88.3% of positive COVID-19 samples, and 99.9% of negative influenza B samples. Since there were not enough cases of influenza B to study, validation confirmed that the test can identify the virus in contrived specimens. The EUA requires the test maker to continue to assess the test’s ability to detect influenza B in real-world settings.

Revisions to two EUAs, for nirmatrelvir-ritonavir (Paxlovid) and molnupiravir (Lagevrio), removing the requirement for positive SARS-CoV-2 test results to prescribe these products. While the FDA continues to recommend that clinicians use viral testing, the agency recognizes that in rare instances, patients with a recent known exposure who develop symptoms may be diagnosed as having COVID-19 even if they have a negative test result. In such instances, the clinician may determine that treatment with authorized therapeutics may be appropriate if the patient reports mild to moderate symptoms and is at high risk for progression to severe COVID-19, including hospitalization.

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### APC Practice Tips

#### 2023 changes to E/M coding: What's new?

By Disha Patel

**W**ith a new year come new changes to coding and documentation for evaluation and management (E/M) services. As a result of advocacy from ACP and other specialty societies, national guidance for coding inpatient E/M care services has been revised to align with earlier reforms to reduce administrative burdens starting Jan. 1. Through our work in the AMA’s CPT and RUC processes, the College informed these changes, and in line with our Patients Before Paperwork Initiative, ACP supported the efforts to simplify coding guidelines.

The revised coding and documentation framework is intended to reduce administrative burden by including CPT code descriptor times, revising interpretative guidelines for levels of medical decision making (MDM), and permitting choice of medical decision making or time to select code level. The use of history and exam to determine code level was also eliminated. However, a face-to-face E/M service is still required to report these E/M codes, and a medically appropriate history and physical examination are expected, where medically appropriate.

What does this mean for you? For 2023, the codes for reporting observation care services (99217-99220) will be deleted and observation care services will be merged into the codes previously used to report only professional services provided for that hospital visit. The codes for each type of service day are shown in Table 1. For more information and coding tips, visit our interactive online training program, Coding for Clinicians (www.acponline.org/coding4clinicians), which prepares you to code smarter and more efficiently.

In addition, the times assigned to each code capture the total time on the date of the encounter by the calendar date. This includes all necessary patient care services performed on the hospital care date, including time required to document the visit and services performed while not with the patient. These are shown in Table 2.

To help relieve burden from coding and documentation requirements, ACP has created a series of expansive coding resources to inform members of how to secure appropriate compensation. Our Inpatient Services Codes resource, at www.acponline.org/inpatient-coding-charts, makes it easy to select and document appropriate levels of services.

To learn more about how ACP continues working to advocate for improved payment for primary care and how code values are determined through the CPT and RUC processes, watch our Informational Webinar series hosted by the College’s Coding and Payment Policy subcommittee, online at www.acponline.org/informational-webinars. ACP believes these new changes will lead to a significant reduction in administrative burdens, and we encourage members to let us know how these reforms may have helped relieve burden in your practice.

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### Table 1. Codes for type of service day

<table>
<thead>
<tr>
<th>Level</th>
<th>Initial Inpatient or Observation Care Day</th>
<th>Subsequent Inpatient or Observation Care Day</th>
<th>Same-Day Admission and Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Low)</td>
<td>99221</td>
<td>99231</td>
<td>99234</td>
</tr>
<tr>
<td>2 (Moderate)</td>
<td>99222</td>
<td>99232</td>
<td>99235</td>
</tr>
<tr>
<td>3 (High)</td>
<td>99223</td>
<td>99233</td>
<td>99236</td>
</tr>
</tbody>
</table>

### Table 2. Times assigned by code

<table>
<thead>
<tr>
<th>Initial Care Day Services (prior to first midnight)</th>
<th>Total time, minimum (minutes)</th>
<th>Subsequent Care Day Services (from midnight up to the next midnight)</th>
<th>Same Care Day Admission and Discharge</th>
<th>Total time, minimum (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>99221</td>
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<td>99236</td>
<td>99236</td>
<td>85</td>
</tr>
</tbody>
</table>

**With a new year come new changes to coding and documentation for evaluation and management (E/M) services.**