Rising Prices of Generic Drugs

As many healthcare providers have noticed, the cost of generic drugs has been increasing over the past couple of years. This is a trend that concerns many in the healthcare arena, as the use of generic medication utilization has become an important component of rational and cost-effective prescribing and dispensing. There are numerous speculations as to why there have been such dramatic increases in prices, but the main factors are agreed—by many experts—to be the result of market forces, namely: lack of competition, lack of access to raw materials, and increased regulatory pressure on manufacturers.

These factors may affect drug prices by a number of means. If the margins are not appropriate, some manufacturers will stop making a certain product. This may result in higher prices charged by those who remain in that market. Other factors have more to do with the supply chain. If the ingredient costs (raw materials) for the drugs become more expensive, manufacturers may pass this on to consumers. And, lastly, some processing plants and facilities have not passed quality tests put in place by the FDA, which may also result in a barring of those facilities’ operations for some time. All three of these factors likely play a part in one way or another, but the net effect is typically a shortage of the drug in question.

Congress has taken notice of this issue and there is a Senate subcommittee currently looking into the issue and they have contacted many generic manufacturers for explanation. As the chart (on the following page) demonstrates, many of these medications are commonly used in the hospice setting, and this highlights the importance of vigilant monitoring of the hospice’s drug expenditures. Things like high-cost limits, for example, may be able to catch these runaway drug costs, for products such as doxycycline, or glycopyrrolate, divalproex, or digoxin—a few of the more commonly seen drugs on the chart.

A Cochrane review reports Tamiflu has been shown to reduce the flu by only about 16.8 hours on average, but has not been proven to prevent hospitalizations or complications of influenza. Evidence is insufficient to support the use of Tamiflu in preventing person-to-person spread of influenza, and has not proven to reduce risk of confirmed pneumonia. In general, there is lack of reliable evidence to support the original claims of its benefits. Evidence from treatment trials showed increased risk of nausea and vomiting; and in prevention trials, there was an increased risk of headaches, psychiatric disturbances, and renal events. The benefit of Tamiflu in hospice patients is not clear, but does not seem to outweigh risks or justify the cost. This medication requires renal dose adjustments in patients with CrCl <60ml/min.

Tamiflu is not on ProCare HospiceCare’s preferred drug list and requires clinical manager approval to be covered.

Reference:
Breeze, K et al. Tamiflu and Relenza: how effective are they? April 2014. The Cochrane Collaboration

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Follow us online and on Twitter to keep up with the latest clinical news and regulatory trends that affect hospice care, or share your own exciting story!
Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs

On October 2, 2014, Rep. Elijah E. Cummings, Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, sent letters to 14 drug manufacturers requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses. Data was provided by the Healthcare Supply Chain Association (HSCA) on recent purchases by group purchasing organizations (GPOs) of ten generic drugs.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Use</th>
<th>Average Market Price Oct. 2013</th>
<th>Average Market Price April 2014</th>
<th>Average Percentage Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline Hyclate (bottle of 500, 100 mg tablets)</td>
<td>antibiotic used to treat a variety of infections</td>
<td>$20</td>
<td>$1,849</td>
<td>8,281%</td>
</tr>
<tr>
<td>Albuterol Sulfate (bottle of 100, 2 mg tablets)</td>
<td>used to treat asthma and other lung conditions</td>
<td>$11</td>
<td>$434</td>
<td>4,014%</td>
</tr>
<tr>
<td>Glycopyrrolate (box of 10 0.2 mg/mL, 20 mL vials)</td>
<td>used to prevent irregular heartbeats during surgery</td>
<td>$65</td>
<td>$1,277</td>
<td>2,728%</td>
</tr>
<tr>
<td>Divalproex Sodium ER (bottle of 80, 500 mg tablets ER 24H)</td>
<td>used to prevent migraines and treat certain types of seizures</td>
<td>$31</td>
<td>$234</td>
<td>736%</td>
</tr>
<tr>
<td>Prevacartatin Sodium (bottle of 500, 10 mg tablets)</td>
<td>used to treat high cholesterol and to prevent heart disease</td>
<td>$27</td>
<td>$196</td>
<td>573%</td>
</tr>
<tr>
<td>Neostigmine Methylsulfate (box of 100 1:1000 vials)</td>
<td>used in anesthesia to reverse the effects of some muscle relaxants</td>
<td>$25</td>
<td>$121</td>
<td>522%</td>
</tr>
<tr>
<td>Benazepril/Hydrochlorothiazide (bottle of 100, 20-25 mg tablets)</td>
<td>used to treat high blood pressure</td>
<td>$34</td>
<td>$149</td>
<td>420%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Use</th>
<th>Average Market Price Nov. 2012</th>
<th>Average Market Price Sept. 2014</th>
<th>Average Percentage Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isuprel (Box of 25, 0.2 mg/mL vials)</td>
<td>used to treat heart attacks and irregular heartbeat</td>
<td>$916</td>
<td>$4,489</td>
<td>390%</td>
</tr>
<tr>
<td>Nitropress (50 mg vial)</td>
<td>used to treat congestive heart failure and reduce blood pressure</td>
<td>$44</td>
<td>$215</td>
<td>388%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Use</th>
<th>Average Market Price Oct. 2012</th>
<th>Average Market Price June 2014</th>
<th>Average Percentage Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin (single tablet, 250 mcg)</td>
<td>used to treat irregular heartbeats and heart failure</td>
<td>$0.11</td>
<td>$1.10</td>
<td>884%</td>
</tr>
</tbody>
</table>

HSCA surveyed average costs paid by four GPOs from October 2013 to April 2014. One GPO provided percentage increases rather than price increases, so the average reflects additional price data not captured by the average market price increase. One GPO provided price information for January 2013 to April 2014. HSCA provided Digoxin prices from National Average Drug Acquisition Cost data maintained by the Centers for Medicaid and Medicare Services.

The prices above are average market prices. Average wholesale price and specific hospice contracts may result in varying price estimates.

Upcoming Lunch and Learn Presentations

March: “Diabetes Management at End of Life” Presenter: Kiran Hamid, RPh and Karen Bruestle-Wallace, PharmD, CGP
Dates: Tuesday, March 10, 2015 at 3:00pm ET; Wednesday, March 11, 2015 at 12:00pm ET

April: “Proper Disposal of Medicine” Presenter: Brett Gillis, PharmD
Dates: Tuesday, April 14, 2015 at 3:00pm ET; Wednesday, April 15, 2015 at 12:00pm ET

RSVP by contacting Suzanne Stewart, Lunch and Learn Coordinator, at 1-800-662-0586 ext. 3303 or sstewart@procarerx.com.

Miss a Lunch and Learn? Log onto PHC website, click on “Education” and “Online Seminar” to listen to audio and view handouts from previous programs (https://phc.procarerx.com/educate/onlineseminar/inl2015).
Overview of the Confusion Assessment Method

Cody Midlam, PharmD, CGP

Delirium is a clinical presentation common in the hospice setting, affecting 10-31% of older patients admitted to a hospital IPU and 11-42% of older adults developing delirium during their hospitalization. There are numerous negative clinical consequences associated with delirium including: prolonged hospitalization, increased use of restraints, increased mortality, and increased risk for developing dementia. The Confusion Assessment Method (CAM) is a standardized and evidenced-based tool which allows clinicians to quickly and accurately recognize delirium. The CAM Algorithm is provided below:

**Feature 1: Acute Onset or Fluctuating Course**  This feature is usually obtained from a family member or nurse and is shown by positive responses to the following questions: Is there evidence of an acute change in mental status from the patient’s baseline? Did the (abnormal) behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?

**Feature 2: Inattention**  This feature is shown by a positive response to the following question: Did the patient have difficulty focusing attention, for example, being easily distractible, or having difficulty keeping track of what was being said?

**Feature 3: Disorganized Thinking**  This feature is shown by a positive response to the following question: Was the patient’s thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

**Feature 4: Altered Level of Consciousness**  This feature is shown by any answer other than “alert” to the following question: Overall, how would you rate this patient’s level of consciousness? (alert [normal]), vigilant [hyperalert], lethargic [drowsy, easily aroused], stupor [difficult to arouse], or coma [unarousable])

The diagnosis of delirium by CAM requires the presence of features 1 and 2 and either 3 or 4. The tool focuses on four features which allow the clinician to distinguish delirium from other types of confusion. CAM is helpful for identifying the presence of delirium; however, it does not assess the severity of delirium and cannot be used for ongoing clinical management of a patient’s condition.

**Source:**

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**News from the Pharmaceutical World continued from page 2**

**Namenda Immediate-release will go generic and patients can maintain access.**

In a Wall Street Journal Article, *Actavis is Ordered to Continue Selling the Namenda Alzheimer’s Pill*, the author, Ed Silverman describes the story of drug maker Forrest Labs (now part of Actavis) and how the company will continue producing the Namenda Immediate-release tablets. The patent on the immediate-release version of Namenda will expire in 2014, meaning the drug will be available generically. The manufacturer has created an extended-release version (Namenda XR) of the drug which is dosed once-daily vs the twice daily dosing regimen of its predecessor. The Namenda XR capsules can also be opened and sprinkled on soft food, the manufacturer reports.

It is important to remember that Namenda (generic memantine) is not typically recommended to be continued in the end of life setting as there are no reports which demonstrate continued efficacy in this setting. If a patient opts to continue Namenda, the immediate-release tablets may be crushed for patients presenting with difficulty swallowing.

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ProCare HospiceCare welcomes all suggestions and comments.  If you would like additional information about our services, have ideas for articles, or wish to submit a comment, email us at resources@procarerx.com.

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