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Sales Distribution Data
We use sales data to examine trends in the distribution of Naloxone

- **IMS Health, IMS National Sales Perspective™**
  - Nationally estimated sales distribution data from wholesalers on volume of drug sold from manufacturers to retail and non-retail markets
  - Captures number of vials/injections sold and total revenue for those sales
  - Nationally projected based on ~85% of the total market
  - **Direct sales, internet sales, and other sales outside of the wholesale pharmacy distribution process are not captured**
Majority of the vials/injections sold of Naloxone are for the 0.4 mg/mL strength

Naloxone Sales By Strength

- **Generic Naloxone 1mg/ml**
- **Generic Naloxone 0.4mg/ml**
- **Evzio**

<table>
<thead>
<tr>
<th>Period</th>
<th>Generic Naloxone 1mg/ml</th>
<th>Generic Naloxone 0.4mg/ml</th>
<th>Evzio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr 2009 - Mar 2010</td>
<td>3.0</td>
<td>2.9</td>
<td>0.1</td>
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<tr>
<td>Apr 2010 - Mar 2011</td>
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<td>0.1</td>
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<tr>
<td>Apr 2011 - Mar 2012</td>
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</tr>
<tr>
<td>Apr 2012 - Mar 2013</td>
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<td>Apr 2013 - Mar 2014</td>
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</tr>
<tr>
<td>Apr 2014 - Mar 2015</td>
<td>3.5</td>
<td>3.3</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Nationally Estimated Number of Vials/Injections of Naloxone, by Strength, Sold to All Settings of Care

Evzio sales have increased since introduction but are still well below other formulations

Evzio Sales by Quarter (July 2014 - March 2015)

Nationally Estimated Number of Vials/Injections of Evzio, Sold to All Settings of Care
Each strength is sold primarily by one company

Nationally Estimated Number of Vials/Injections of Naloxone, by Strength and Manufacturer, Sold to All Settings of Care

In the last 5 years, sales to outpatient settings have increased by 72%.

April 2009 - March 2010
N=2.8 million vials/injections

April 2014 - March 2015
N=3.2 million vials/injections

Includes EMS providers

Nationally Estimated Number of Vials/Injections of Naloxone Sold by Setting of Care
Most of these additional outpatient sales occurred in 2014-2015

Nallyoxone Sales By Strength, **Outpatient** Only

- Generic Naloxone 1mg/ml
- Generic Naloxone 0.4mg/ml
- Evzio

Nationally Estimated Number of Vials/Injections of Naloxone, by Strength, Excluding Non-Federal Hospitals

Sales to **outpatient** settings also occur from a small number of companies

Nationally Estimated Number of Vials/Injections of Naloxone, by Strength and Manufacturer, Excluding Non-Federal Hospitals

Pricing Data
We use the same data source to analyze trends in Naloxone’s price

• Reminder: Data may not fully capture community use if direct sales are occurring from manufacturers to EMS providers
• Captures **invoice price**:  
  • Average price paid by pharmacies or hospitals to wholesalers  
  • Includes any discounts that occur at the point of sale
• For this analysis, we continue to display only distribution to outpatient settings of care (excludes non-federal hospitals)
• We limit our analysis to the highest revenue formulation for a company and molecule in CY 2014
Price for the 0.4 mg/mL strength increased in January 2014

- Hospira’s product increased in price by about 50% in January 2014
- Mylan introduced its product in March 2014 and has followed a similar pricing trend to Hospira
Price for the 1 mg/mL strength increased in September 2014

- Kaleo’s auto-injector was introduced in July 2014 and was priced at about 4 times as much as the Amphastar product
- Amphastar’s price increased by about 60% in September 2014
These price increases are part of a recent trend in generic injectable drugs

• We conduct the same analysis for all generic injectable drugs in the dataset, and end up with 1,109 formulations across 354 molecules in CY 2014
• We calculate percent changes in invoice price for each formulation on a month to month basis in CY 2014
• We find that 24.6% of molecules had at least one billing unit in CY 2014 with a monthly price increase larger than 60% (Amphastar’s price increase)
• 9.6% of formulations had a monthly price increase larger than 60%
Medicare pricing data show a similar trend to the 0.4 mg/mL strength

- **Average Sales Price (ASP) – Medicare Part B**
  - Captures a volume-weighted average price (net of discounts) for all covered drugs that are subject to Medicaid rebates
  - Does not distinguish between strengths, and is **lagged by 2 quarters**
We are limited in our ability to analyze Naloxone’s market by the available data

- Direct sales from manufacturers to EMS providers or other organizations are not captured in our sales distribution data
- Sales distribution data do not directly measure drug utilization
  - Provide an estimate of purchases by channels of distribution (supply)
  - May proxy for utilization if facilities purchase drugs in quantities reflective of patient use
- Cannot determine which indication, clinical uses, or types of organizations within each distribution channel are driving the observed changes
Summary

- Sales of Naloxone to outpatient settings increased by 72% in the last 5 years, while sales to inpatient/ER settings declined by 12%
- Each of the 0.4 mg/mL and 1 mg/mL strengths are primarily sold by one company
- Price increases occurred in January 2014 for the 0.4 mg/mL strength and in September 2014 for the 1 mg/mL strength. Since then, prices have remained elevated.
- 25% of generic injectable molecules had a monthly price increase at least as large as the 1 mg/mL strength in CY 2014