Hope in the Midst of Big Pharma Greed
ICER and PCSK9 Inhibitors

I grow increasingly skeptical and frankly cynical at the pharmaceutical industry’s approach to pricing their drugs—“What will the market bear?”

Then on February 15th, the Institute for Clinical and Economic Review (ICER) released their evaluation of the cost effectiveness of the PCSK9 inhibitor, alirocumab (Praluent) used for the treatment of high cholesterol in certain populations. ICER is an independent nonprofit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs.

ICER’s Chief Medical Officer Dr. David Rind commented, “When added to maximally tolerated statin therapy in patients with a recent acute coronary event and a LDL of 70 or higher, alirocumab appeared to reduce cardiovascular events by 15% and appeared to reduce all-cause mortality by a similar amount.” (Can’t calculate the NNT from the data they provide) Based on these new analyses, ICER is revising its value-based price benchmark ranges for alirocumab to $2300 – $4000 per year. These ranges reflect commonly cited cost-effectiveness ratios of between $100,000 and $150,000 per quality adjusted life-year (QALY) gained.

And about the same time, Regeneron and Sanofi announced that the annual US price of alirocumab would be reduced to $5850, down from $14,600 when the drug was first introduced in 2015.
My Take:
Was the 40% price reduction a coincidence with ICER’s evaluation? Is cost effectiveness data starting to have an effect on Big Pharma? I applaud ICER’s efforts.

The price decrease is great news, particularly in the face of the recent “Here we go again” ACA/ AHA lipid guidelines that suggest going back to monitoring LDL levels and targeting a percentage reduction LDL. These updated guidelines were made without any input from primary care physicians who manage most hyperlipidemic patients. The ACP and the AAFP did not participate in creating or endorsing these lipid guidelines, just as they did not participate in the recent, aggressive hypertension guidelines from the ACC/AHA.

Drs. Steve Nolan and Zach Kareus, my Pharm D colleagues at Rocky Mountain Health Plans presented the following three topics at the February 2019 PharmaSuitables in Grand Junction. The work is theirs. The opinions are mine. Thank you, Steve and Zach.

Advair Diskus
Two New Generics

Mylan Pharmaceuticals has launched the first generic to Advair Diskus: Wixela Inhub. I agree the Mylan drug namer was out to lunch. The good news is that Wixela Inhub will be priced at a 70% discount to Advair Diskus.

– $93 for the 100mcg/50mcg inhaler
– $116 for the 250mcg/50 mcg inhaler
– $153 for the 500mcg/50 mcg inhaler

Prasco Labs has also released an authorized generic which will also likely have a steep price discount versus Advair.

ZTlido 1.8%
A New Lidocaine Patch

Marketed to be worn during moderate exercise, ZTlido is FDA approved only for post-herpetic neuralgia. Scilex Pharmaceuticals claims better adhesion with ZTlido in a head to head trial (undiscoverable poster session, Las Vegas 2018) with Lidoderm. The ZTlido patch is lighter and thinner than the Lidoderm patch, but delivers the bioequivalent dose of lidocaine. ZTlido patches are to worn up to 12 hours per day with a limit of 3 patches at one time.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost per patch</th>
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<tbody>
<tr>
<td>ZTlido 1.8%</td>
<td>$10.77</td>
</tr>
<tr>
<td>Lidocaine 5% patch</td>
<td>$6.47</td>
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<tr>
<td>Lidoderm 5% patch</td>
<td>$14.30 ($5.17 in Canada)</td>
</tr>
<tr>
<td>OTC Healthwise 4% patch</td>
<td>$1.00</td>
</tr>
<tr>
<td>OTC Salonpas 4% patch</td>
<td>$1.70</td>
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My Take: Amazon Prime customers give both the Healthwise and Salonpas patches high marks. Are lidocaine patches a reasonable analgesic alternative for non-specific muscular pain as the OTC users suggest?
Primatene Mist is Back!

- Primatine Mist was taken off the market in 2011 because it used a CFC propellant.
- It has now been reformulated with HFA and the FDA has cleared it for marketing for “temporary relief of mild, intermittent asthma” down to age 12.
- The active ingredient is 0.125mg epinephrine per spray. Epinephrine is not a recommended asthma treatment under NIH’s Guidelines.
- The FDA has struggled with safety concerns with the device and concerns over patients self-treating a serious chronic illness.
- In November 2018, the FDA was satisfied that most patients would be able to safely use the device, while acknowledging that risks remain.
- Inhaler must be shaken and a dose dispensed into the air before each inhalation.
- The maximum labeled dose is 8 inhalations per day.
- The inhaler must be cleaned every day to prevent clogging and/or medicine buildup.
- Most professional lung and asthma associations, including the AAP have protested the FDA’s decision to approve Primatene Mist.
- Primatene Mist is available in pharmacies now and the cost is about $25 per inhaler.

**My Take:** I am chronically critical of the FDA, but with Primatene Mist, I am sympathetic to their dilemma. In an ideal world (most industrial countries other than our own) one would not have to deal with a large uninsured/underinsured asthmatic population with poor access to medical care. Albuterol HFA inhaler is available for $30 with a prescription and a $100+ clinician visit.