Biosimilars slated to arrive in the U.S. this year

After years of use in Europe, the first two biosimilar medications are slated to reach the American market in 2015. Biosimilars are lower-cost alternatives for specialty medications which treat the most complex and chronic conditions. Once these drugs hit the market, they are slated to heavily impact the specialty drug category and have the potential to save both members and employers billions of dollars over the next decade.

In July, the Food and Drug Administration (FDA) accepted the first two applications from drug companies that want to produce biosimilars for patients in the U.S. The first filing seeks approval for biosimilar filgrastim, a treatment used to decrease rates of infection in cancer patients during chemotherapy. The drug, Zarzio®, would compete with Neupogen®. The second application, filed one month later, seeks approval for Remsima®, used to treat rheumatoid arthritis, Crohn’s disease and other inflammatory conditions. Remsima® is a biosimilar to Remicade® (infliximab).

“Biosimilars are expected to cost roughly 30 percent less than their parent drugs,” said Mike Reilly, president of Pharmacy Benefit Directions. “The FDA acceptance of these two applications is welcome news, as biosimilars could do for specialty drugs what generics did for traditional oral solid pills, which is lower the cost for safe and effective treatments for our members.”

If these drugs are approved by the FDA, they could hit the market in May and June, respectively. At this time, it is not known when the products would be accessible to patients as questions remain over naming issues and state drug substitution laws.

Any biologics would be strictly reviewed for safety, efficacy and cost by our Pharmacy and Therapeutics (P&T) Committee, which is made up of physicians and pharmacists practicing in our community and members of our staff who are well-versed in the needs of both our employers and members. We will continue to keep you updated on the status of approved biosimilars and any applicable state or federal regulations which apply.

PBD welcomes new account manager

Pharmacy Benefit Dimensions is pleased to announce that Amy Buchholz has joined our Account Management team. As an account manager, she will work with both employers and brokers to provide overall account management, including contracting, reporting, benefit modeling, plan performance, and open enrollment meeting assistance.

Amy comes to Pharmacy Benefit Dimensions with extensive experience in account management, having served as an account manager for small accounts at our parent company, Independent Health, since July 2009. In that position she was responsible for retention and growth of membership for more than 700 small businesses, where she applied her extensive experience in the health care industry to build relationships with clients throughout Western New York. While with the small accounts team, she was recognized as Account Manager of the Year for Small Group Sales in 2010, 2011 and 2012 and was selected for the Independent Health Emerging Leaders Program.
Industry update: Specialty medication market expanding

In the past few years, the landscape of medications has changed extensively, with a focus shifting from traditional medications to the development of specialty medications. Below are a few medications you will be hearing more about in the coming months:

- Two new drugs to treat patients with chronic hepatitis C virus (HCV) are now on the market. The first, Viekira Pak™, combines three new drugs (ombitasvir, paritaprevir and ritonavir) packaged with dasabuvir tablets. The second drug, Harvoni®, combines sofosbuvir (Sovaldi®) and ledipasvir in one tablet. Both products have been shown to cure patients with genotype 1 HCV. In December, our Pharmacy and Therapeutics (P&T) Committee approved the addition of Harvoni® as a Tier 3 drug (prior authorization and specialty pharmacy apply) on the PBD drug formulary. The committee will review Viekira Pak™ at its March 2015 meeting.

- Researchers are currently developing a new class of biologic drugs that lower cholesterol through inhibition of the PCSK9 protein. These drugs would be used for patients with a rare inherited disease called familial hypercholesterolemia, as well as individuals who have had a poor response or intolerance to traditional cholesterol lowering medications. These medications will be self-injected and administered every few weeks. Therefore they are expected to compete with the widely used class of statin medications which are taken daily. The first of these drugs are expected to hit the market this summer.

- An application is on file with the Food and Drug Administration (FDA) seeking approval for a new drug to treat cystic fibrosis. The drug is a combination of Kalydeco™ and lumacaftor and is designed for individuals ages 12 and older who have two copies of the most common mutation of cystic fibrosis, F508del. The manufacturer has requested a priority review of the drug, which could reduce the FDA approval time from approximately November to July 2015. If approved, it could be on the market as early as this summer.

Please note: New medications are always reviewed for safety, efficacy and cost by our P&T Committee to determine if and/or where they should be placed on our drug formulary.

Tailoring benefits to meet your needs

The prescription benefit is one of the most utilized health care benefits, and as a result, has a significant impact on total health care costs. Through formulary and utilization management, Pharmacy Benefit Dimensions is able to help employers control drug costs while allowing members to get the right drug clinically, at the right price.

Your Pharmacy Benefit Dimensions Account Manager is available to work with you to identify ways to manage costs through tailored benefit designs and programs. Examples include:

- **Specialty Copay Assistance Program (SCAP)**: Members utilizing a specialty drug in the Specialty Copay Assistance Program will have a $0 copayment when they obtain their drugs through Reliance Rx. Employers realize savings through manufacturer assistance. There are currently 10 specialty drugs eligible for SCAP.

- **Member Pays the Difference**: A program where members taking a brand drug in Tier 3 of the formulary that has a generic equivalent in Tier 1 would pay their Tier 3 copayment plus the difference in cost between the brand-name drug and the generic drug. This program encourages the use of generic drugs but still allows members access to brand-name drugs at no additional cost to the plan.

- **Mandatory Mail-Order**: Members utilizing a retail pharmacy for refills on maintenance medications (drugs normally prescribed for long-term chronic conditions) would be required to utilize one of our mail-order providers. As incentive to using mail-order, members receive up to a 90-day (3-month) supply of these maintenance medications for the cost of 2 or 2.5 monthly copayments, dependent on benefit design. Employers recognize savings due to Pharmacy Benefit Dimensions’ negotiated mail-order rates.

As always, the cost effectiveness of these programs is primarily dependent on a group’s benefit design. To learn more about any of these programs, please contact your Pharmacy Benefit Dimensions Account Manager.

PBD offers an extensive pharmacy network

Pharmacy Benefit Dimensions (PBD) members have access to more than 60,000 pharmacies across the country in addition to the many local independent pharmacies. Here are just some of the pharmacies that are part of the PBD network:

- A&P
- BiMart
- Costco
- CVS
- Giant Eagle
- Hannaford Stores
- Harris Teeter
- Hy-Vee
- Kinney
- Kmart
- Price Cutter
- Publix
- Rite Aid
- Safeway
- Target Stores
- Tops Markets
- Walgreens
- Wal-Mart Pharmacy
- Wegmans Pharmacy
- Weis Market

If your employees are unsure of their pharmacy’s participation, please have them visit our website at [www.pbdrx.com](http://www.pbdrx.com) and click on “Find a Pharmacy.”
Changes made to the PBD drug formulary

The Independent Health Pharmacy and Therapeutics (P&T) Committee, which is made up of physicians and pharmacists practicing in our community and members of our PBD staff, meets quarterly to review and make changes to our drug formulary. All drug tier decisions made by the committee are based on efficacy and safety first, and economics only after clinical effectiveness has been determined. Below are changes to the PBD drug formulary that were recommended by the P&T Committee at its December 2014 meeting.

The following medications were added to the formulary:

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG</th>
<th>ACTION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>Arnuity Ellipta</td>
<td>Addition – Tier 1 or preferred brand</td>
<td>Age limit minimum 12-year-old applies</td>
</tr>
<tr>
<td>Anti-HIV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP3A Inhibitor</td>
<td>Tybost</td>
<td>Addition – Tier 2 or preferred brand</td>
<td>ST applies</td>
</tr>
<tr>
<td>Protease Inhibitors</td>
<td>Vitekta</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following new generics are available:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isentress</td>
<td>raltegravir</td>
<td>Antivirals</td>
</tr>
<tr>
<td>Patanase</td>
<td>olopatadine</td>
<td>Nasal agent</td>
</tr>
<tr>
<td>Protopic</td>
<td>tacrolimus</td>
<td>Dermatologicals</td>
</tr>
<tr>
<td>Selzentry</td>
<td>maraviroc</td>
<td>Antivirals</td>
</tr>
<tr>
<td>Stromectol</td>
<td>ivermectin</td>
<td>Anthelmintics</td>
</tr>
<tr>
<td>Valcyte</td>
<td>valaganciclovir</td>
<td>Antiviral</td>
</tr>
</tbody>
</table>

The following recommendations were made:
- Trulicity – Tier 3, ST applies except endocrine
- Movantik – Tier 3, ST applies
- Harvoni – Tier 3, PA, SP applies
- Esbriet – Tier 3, PA, SP applies
- OFev – Tier 3, PA, SP applies
- Auryxia – Tier 3
- Xigduo XR – NF
- Mitigare – Tier 3
- Akynzeo – Tier 3, ST, QL applies
- Hysingla – NF
- Saxendra – NOT COVERED
- Contrace – NOT COVERED

The following changes in coverage were approved:
- Vicodin/Xodol – Move to NF as of April 1, 2015
- Carac (fluorouracil 0.5% cream) – New generic to Tier 3, ST through other fluorouracil
- Picato gel – Remove PA
- Breo Ellipta – Move to tier 2
- Thiola – PA applies as of April 1, 2015
- Dibenzyline – PA applies as of April 1, 2015
- Fluoxetine 20/40mg tabs – Move to NF -2016
- Actiq brand – Move to NF as of April 1, 2015
- Epiw HBV– Remove PA

The following Injectable Drugs were reviewed and approved as follows:
- Keytruda – PA Applies
- Hyqvia – PA Applies
- Iluvien – PA Applies

The following Multisource Brand Name Drugs will move to Non-Formulary, effective April 1, 2015 (generic equivalents will still be available):
- Arixtra
- Lovenox
- Persantine
- Ticlid
- Agrylin
- Pletal
- Trental
- Ciloxan
- Ocuflox
- Quixin
- Viorptic
- HIMS
- Pred Forte
- Tobradex susp
- Alphagan P 0.15%
- Betagan
- Cosopt
- Diamox
- Iopidine
- Optipranolol
- Timoptic
- Timoptic XE
- Trusopt
- Xalatan
- Zioptan
- Acular
- Acular LS
- Alamast
- Elestat
- Mydfrin
- Ocufrin
- Optivar
- Voltaren
- Besivance
- Vigamox
- Moxeza
- Zymaxid

Key:
NF = Non-formulary
SP = Specialty Medication
PA = Prior Authorization Required
ST = Step Therapy
QL = Quantity Limit