



integrated pharmacy services

# LDI Specialty Drug News

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## Focus on Medical Specialty Benefits and Management

With no new legislative or regulatory changes impacting healthcare plans this year, most employers are looking at ways to manage their specialty medication spend.

While some plans have implemented a 4th tier formulary within their prescription drug benefit to accommodate the high cost of specialty drugs, little else has been done to help manage the cost. As the pipeline for specialty medication continues to grow it is now more important than ever that healthcare plans look to the clinical and cost management side of specialty pharmaceuticals instead of just shifting dollars into another tier benefit.

In order for a plan to determine where they need to focus their attention they must first know where they are in relation to specialty drug spend for their group. Most employers will look to their PBM for

reporting on specialty drug fulfillment. However, that is only a small slice of the pie. In order to truly manage specialty drugs, plans also need to look to their medical benefits. Current physician practice is to bill specialty drugs utilizing HCPCS codes. By identifying which HCPCS codes represent specialty drugs, a payer can produce reports that reflect how many specialty medications filtered through the medical plan. By combining the data from

both the PBM and medical side, a plan can then determine their true exposure to specialty pharmaceuticals and get a handle on their approximate per member per month costs and what their trend has been year to year. Typically 0.5% to 2% of any population will utilize specialty medications but the impact in dollar amounts can be 10% to 20% of the total cost of the plan.

*It is now more important than ever that healthcare plans look to the clinical and cost management side of specialty pharmaceuticals*

Once a plan knows where their



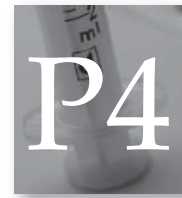
Recent FDA Approvals of Specialty Medications



February Health Observances



2008 Pipeline is Full of Specialty Drugs & Compounds



Specialty Medication Listing by Disease/Condition

costs are the next step is to review the data to determine if the most cost effective management of the benefit was utilized.

*Questions to ask are:*

- Was case management implemented? If so, what steps were taken to reduce the cost of the specialty medication?
- Is the medication FDA approved for the intended use or was it being used off-label or for experimental purposes?
- Did the treatment plan prescribed meet all of the protocols?
- Should step-therapy or pre-authorization for specialty drugs be implemented?
- Did the patient remain compliant with their medication regimen thereby eliminating possible ER visits or hospital admissions?
- Could a specialty pharmacy have provided the drug at a better discount than that given by the preferred provider network or retail pharmacy?
- Was there follow-up with the patient to ensure that proper training and safety precautions were met?

By reviewing data from both the PBM and medical benefits a plan

*-continued, page 3*

## FEBRUARY AWARENESS

**-National American Heart Month**

**-National Child Dental Health Month**

**-Wise Healthcare Consumer Month**

**-Shamrocks Against Dystrophy for the  
Muscular Dystrophy Association**

## Recent FDA Approvals of Specialty Medications

**Akorn, Inc.** announced on January 30, 2008 that the Food and Drug Administration has granted approval for Akorn's Abbreviated New Drug Application (ANDA) for Calcitriol injection, 1mcg/mL and 2mcg/mL.

Calcitriol injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It significantly reduces elevated levels of parathyroid hormone. Annual sales of Calcitriol were approximately \$6 million in 2007, according to IMS sales data.

Akorn has announced that the drug will be manufactured in their facility in Decatur, IL and the expected launch will be in the second half of 2008.

**Tibotec Therapeutics** announced on January 18, 2008 that the Food and Drug Administration has approved Intelence for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor (NNRTI) and other antiretroviral agents. Intelence is an NNRTI. NNRTIs work by blocking reverse transcriptase, an enzyme that HIV needs to make more copies of itself.

Intelence is available as 100 mg oral tablets. The usual dose is 200 mg twice daily following a meal. Treatment cost estimates are approximately \$21.80 per day or \$7,957 per year.

**BioMarin Pharmaceutical Inc.** received FDA approval on December 13, 2007 for Kuvan for treatment of phenylketonuria (PKU). Phenylketonuria (PKU) is a genetic disorder that is characterized by an inability of the body to utilize the essential amino acid, phenylalanine. "Essential" amino acids can only be obtained from the food we eat as our body does not normally produce them.

Kuvan will be distributed primarily through specialty pharmacies. Each 100 mg tablet will cost an average of \$29 with an annual cost of approximately \$57,000 for an average patient.

**Genzyme Corp.** has announced on December 17, 2007, FDA granted supplemental indication for Thyrogen as a combination therapy with radioiodine to destroy remaining thyroid tissue in patients who have had a cancerous thyroid removed. A company spokesperson says that the pricing will be approximately \$1,500 per treatment. Patients typically undergo one procedure.

## 2008 Pipeline Is Full of Specialty Drugs and Compounds

*Experts agree that 2008 will be a good year for specialty drug approvals. "Specialty drugs have taken the industry by storm, essentially becoming their own trend drivers", states Lon Castle, Pharm. D.*

In the past 23 years, 254 biotech drugs have been approved for 385 indications. By the year 2010, half of all FDA approvals will be for specialty drugs. Avastin alone is currently involved in 130 clinical trials, covering 25 different tumors.

Emerging therapies include immunomodulators for inflammatory diseases such as Crohn's disease, lupus, rheumatoid arthritis and multiple sclerosis. Several of the immunomodulators which are currently in Phase III trials are expected to be FDA approved in 2008. Golimumab (Centocor/Schering-Plough) is one such drug that is being studied for rheumatoid arthritis and will likely receive approval in the second half of 2008. The agent is similar to Remicade, however, rather than being an IV infused product it offers the advantages of a subcutaneous injection.

New antibacterial agents to help fight so-called "superbugs" are in desperate need but adequate activity

against these gram-negative organisms appears nowhere in sight. Currently there is one drug that may hold some hope. Doripenem (Doribax, Ortho-McNeil) is currently approved only for complicated intra-abdominal and urinary tract infections. Clinicians are expecting doripenem to be approved for nosocomial gram-negative infections including ventilator-associated and nosocomial pneumonia.

**There has been a 25% increase in the development of oral drugs that target particular cancers more effectively.**

In general, there has been a 25% increase in the development of oral drugs that target particular cancers more effectively. Drugs like satraplatin (Spectrum Pharmaceuticals) under development for hormone refractory prostate cancer, and vatalanib for colon cancer will bring about more patient-directed therapy. Treatment of cancer may soon be similar to treatment of HIV as patients may be treated with an individualized cocktail of pharmacologically complementary oral drugs. New laboratory tests are being devised that will allow physicians to determine which mix of cancer drugs are best suited to treat each individual patient.

*\*Source: Drug Topics*

### *continued, Focus on Medical Specialty Benefits and Management-*

will be better equipped to make decisions which will impact the bottom line costs of specialty medications. By implementing clinical and cost management protocols, healthcare plans will be better equipped to control specialty drug spend even as the market for these drugs continues to grow. Demand will remain high for specialty drugs and costs are projected to continually increase. The share of biologics in the pharmaceutical market was 15.3% in 2005 compared to the projected 21.6% by 2010.\* Employers that make decisions now on how their plans will treat specialty medications will see a more cost effective use of healthcare dollars.

Let LDI Integrated Pharmacy Services help you to better manage specialty medications. **Contact LDI at (866) 516-2121.**  
*\*Source: Drug Topics*

*For more information regarding LDI's Specialty Newsletter, please contact us:*

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# Specialty Medication Listing by Disease/Condition

## AIDS/HIV

Daunoxome  
Doxil  
Intron A  
Roferon-A  
Serostim  
Taxol  
Fuzeon

## Alpha1 - Proteinase Inhibitor Deficiency

Aralast  
Prolastin  
Zemaira

## Antihemophilic Agents

Antihemophilic Factor  
Advate  
Alphanate  
Bioclalte  
Helixate FS  
Hemofil M  
Humate P  
Hyate C  
Koate DVI  
Kogenate FS  
Monarc M  
Monoclate P  
Recombinate  
ReFacto

## Anti-nausea

Aloxi  
Anzemet  
Emend  
Kytril  
Zofran

## Asthma

Xolair

## Cancer/Related

Adriamycin  
Adrucil  
Alkeran  
Aredia  
Avastin  
BiCNU  
Blenoxane  
Busulfex  
Campath  
Camptosar  
Cerubidine  
Cosmegen  
Cytarabine  
Cytoxan  
Depocyt

Doxil  
DTIC-Dome  
Eligard  
Ellence  
Erbitux  
Ethyol  
Faslodex  
Fludara  
Gemzar  
Gleevec  
Herceptin  
Hycamtin  
Idamycin  
IFEX  
Intron A

Leucovorin  
Leukine  
Leustatin  
Lupron Depot  
Lupron Depot-Ped  
Mesnex  
Mustargen  
Mutamycin  
Mylotarg  
Navelbine  
Nexavar  
Nipent  
Novantrone  
Oncaspar  
Ontak  
Paraplatin  
Platinol AQ  
Proleukin  
Rituxan  
Roferon-A  
Sutent  
Tarceva  
Taxol  
Taxotere  
Temodar  
Thyrogen  
Toposar  
Trelstar Depot  
Trelstar LA  
Trisenox  
VePesid  
Vinblastine  
Vincasar  
Vumon  
Xeloda  
Zanosar  
Zoladex  
Zometa

## Contraceptives

Depo-Provera

## Crohn's Disease

Remicade

## Dystonia

Botox  
Myobloc

## Factor IX Concentrates

Alphanine SD  
Benefix  
Mononine  
Profilnine SD  
Proplex T  
Bebulin VH

## Gaucher's Disease

Ceredase  
Cerezyme  
Zavesca

## Growth Hormone Deficiency

Genotropin  
Humatrope  
Norditropin  
Nutropin  
Nutropin AQ  
Saizen

## Hematologics

Arixtra  
Aranesp  
Epogen  
Fragmin  
Innohep  
Lovenox  
Neulasta  
Neumega  
Neupogen  
Procrit

## Hepatitis C

Copegus  
Infergen  
Intron A  
Pegasys  
Peg-Intron  
Rebetron  
Roferon-A

## Hormone Deficiency

Delatestryl  
Delestrogen  
Depo-Estradiol  
Depo-Testosterone

## Hunter Syndrome

Elaprase

## Primary Immunodeficiency

Carimune NF  
Gamimune N  
Gammagard S/D  
Gammar-P  
Gamunex  
Iveegam EN  
Panglobulin  
Panglobulin NF  
Polygam S/D  
Venoglobulin-S

## Miscellaneous

Alferon-N  
Milrinone  
Zincard

## Multiple Sclerosis

Avonex  
Betaseron  
Copaxone  
Novantrone  
Rebif  
Tysabri

## Osteo/ Rheumatoid/ Psoriatic Arthritis

Enbrel  
Humira  
Hyalgan  
Kineret  
Orencia  
Remicade  
Supartz  
Synvisc

## Osteoporosis

Forteo  
Miacalcin

## Psoriasis

Amevive  
Enbrel  
Raptiva  
Remicade

## Respiratory Syncytial Virus

Synagis

## Rh Hemolytic Disease

BayRho-D  
Micro-Rhogam  
Rhogam  
WinRho-SDF