A publication created especially for our clients and associates, delivering up-to-date information about brand-name and generic medication, medical products, and other pharmaceutical-related information collected from key government and industry sources.

## Products Added to the PML

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Therapeutic Class</th>
<th>Effective Date</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| Baraclude® tablets | entecavir | Antiviral agent | 08/15/09 | • The American Association for the Study of Liver Disease (AASLD) recommends Baraclude as a first-line medication for treatment-naïve patients and treatment-experienced chronic hepatitis B patients.  
• Clinical trials demonstrate safety and efficacy over other agents in this class. |

## Other Changes to the PML

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Therapeutic Class</th>
<th>Indications</th>
<th>Effective Date</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adcirca™ tablets</td>
<td>tadalafil</td>
<td>Pulmonary arterial hypertension (PAH) agent</td>
<td>Treatment of PAH (WHO Group I) to improve exercise ability</td>
<td>08/10/09</td>
<td>Added to Specialty PBM list.</td>
</tr>
</tbody>
</table>
## Recent Food and Drug Administration (FDA) warnings and health news for patients and healthcare professionals

<table>
<thead>
<tr>
<th>Drug/Issue</th>
<th>Date</th>
<th>News Event(s)</th>
<th>Member/Client Impact</th>
<th>Strategic Rationale</th>
<th>Action Needed to Implement</th>
</tr>
</thead>
<tbody>
<tr>
<td>None to report</td>
<td>None to report</td>
<td>None to report</td>
<td>None to report</td>
<td>None to report</td>
<td>None to report</td>
</tr>
</tbody>
</table>

### New Products*

<table>
<thead>
<tr>
<th>Drug/Manufacturer</th>
<th>Therapeutic Class</th>
<th>Indication(s)</th>
<th>Date</th>
<th>Projected Launch</th>
<th>Comments</th>
<th>Programs Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New FDA-Approved Agents</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>None to report</td>
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<td>None to report</td>
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</tr>
<tr>
<td><strong>New Dosage Forms and Combinations</strong></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
| **Acuvail™** (ketorolac) 0.45% ophthalmic solution/Allergan | Ophthalmic agent | Treatment of pain and inflammation following cataract surgery | 07/22/09 | Unknown | • Preservative-free formulation of ketorolac  
• Contains carboxymethylcellulose, which allows the drug to adhere to the ocular surface and enhances comfort | P&T review planned.  
MedMonitor® Complete will update lists as needed. |
| **Onsolis™** (fentanyl) buccal soluble film/Meda | Narcotic analgesic agent | Treatment of breakthrough cancer pain | 07/16/09 | Fourth quarter of 2009 | Small, dissolvable polymer film for application to the inner lining of the cheek | P&T review planned.  
Will evaluate for a medication management program when available.  
MedMonitor® Complete will |

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CPA = Clinical Prior Authorization  
SPA = Specialty Prior Authorization  
MUE = Medication Use Evaluation  
RDUR = Retrospective Drug Utilization Review  
PIT = Place in Therapy
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<tr>
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</tr>
</thead>
</table>
| **Sumavel™ DosePro™** (sumatriptan) injection/ Zogenix | Antimigraine agent | Treatment of migraine and cluster headache                                   | 07/15/09 | Unknown          | Needle-free delivery system to treat cluster headache and acute migraine with or without aura | • P&T review planned.  
• Migraine CPA available.  
Clients without this program can discuss medication management strategies with their account executives.  
• MedMonitor® Complete will update lists as needed. |
| **Forteo®** (teriparatide [rDNA origin]) injection/Lilly | Osteoporosis agent | Treatment of osteoporosis associated with sustained, systemic glucocorticoid therapy in men and women at high risk of fracture | 07/22/09 | Available        | Forteo is also indicated for treatment of postmenopausal women with osteoporosis and to increase bone mass in men with primary or hypogonadal osteoporosis. | • Forteo is preferred. No changes planned.  
• MedMonitor® Complete will review for conflict edit and list updates.  
• Osteoporosis                                                                 |

**New FDA-Approved Indications**

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<tbody>
<tr>
<td><strong>Tekturna HCT®</strong> (aliskiren/hydrochlorothiazide) tablets/Novartis</td>
<td>Antihypertensive agent</td>
<td>Initial treatment of hypertension in patients who are likely to require multiple agents to achieve goal</td>
<td>07/16/09</td>
<td>Available</td>
<td>Combination of Tekturna®, a direct renin inhibitor, with a thiazide diuretic</td>
<td>Forteo SPA in place. Clients without this program can discuss medication management strategies with their account executives.</td>
</tr>
</tbody>
</table>
| **Tri-Lo-Sprinetec™** (ethinyl estradiol/norgestimate) tablets/ Tева | Oral contraceptive agent | Prevention of pregnancy | 06/29/09 | TBD             | • Initially launched on 07/01/09 but ceased on 07/07/09.  
  • Teva and Ortho McNeil Janssen have extended their agreement to cease shipments of generic versions of Ortho Tri-Cyclen® Lo, until the Court's ruling on the motion for preliminary | Generic products remaining on the market may be dispensed and are available on lowest copay tier.  
  • Contraceptives CPA available.                                                                                                           |
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<td>injunction or 07/29/09, whichever is earlier.</td>
<td>Clients without this program can discuss medication management strategies with their account executives.</td>
</tr>
</tbody>
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* Note: If FDA-approved, agents are under P&T review and reside on the third tier.

**Pipeline Analysis**

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<td></td>
<td></td>
<td></td>
<td>None to report</td>
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</tr>
</tbody>
</table>

First-Time Generic Drugs in the Pipeline

None to report

Information for *Mortar & Pestle* is compiled by Walgreens Clinical Information Services and obtained from the following sources (with secondary-source links provided):

- Food and Drug Administration (www.fda.gov)
- American Society of Health-System Pharmacists® (www.ashp.org)
- P&T Community (www.ptcommunity.com)
- Pharmaceutical News Harvest™ (www.internetdrugnews.com)
- Drugs.com™ (www.drugs.com)
- Pharmacy OneSource® (www.pharmacyonesource.com)

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