



## Truven Health Analytics™ Micromedex® Solutions Clinical Content Updates

### November-December 2015 and January 2016 Selected Content Updates

<b>Selected New Drug Approvals</b>	
<b>FDA Approvals – New Monographs and Patient Medication Instructions</b>	
<b>Topic / Title</b>	<b>Implication</b>
Alectinib (Alecensa®)	Approved to treat metastatic ALK-positive non-small cell lung cancer in patients who are intolerant of or had disease progression on crizotinib.
Antihemophilic factor VIII (recombinant) pegylated (Adynovate™)	Approved to treat, control, and prevent of bleeding episodes in patients 12 years or older with hemophilia A. Adynovate™ lasts longer and helps reduce the frequency of injections compared to unmodified antihemophilic factor.
Bendamustine (Bendeka™)	A 10-minute IV infusion approved to treat patients with chronic lymphocytic leukemia or indolent B-cell non-Hodgkin lymphoma
Cobimetinib (Cotellic™)	Approved, in combination with vemurafenib, to treat patients with unresectable or metastatic melanoma who have a BRAF V600E or V600K gene mutation. Cobimetinib is not indicated to treat patients with wild-type BRAF melanoma.
Daratumumab (Darzalex™)	Indicated as a single agent to treat multiple myeloma in patients who have received at least 3 previous lines of treatment.
Dexlansoprazole (Dexilant® SoluTab)	Approved to treat heartburn associated with GERD and healed erosive esophagitis. The once-daily delayed-release disintegrating tablets will provide 2 separate releases of the drug.
Elbasvir/grazoprevir (Zepatier™)	Approved, with or without concomitant ribavirin, to treat chronic hepatitis C genotypes 1 and 4
Elotuzumab (Empliciti™)	Approved, in combination with lenalidomide and dexamethasone, to treat patients with multiple myeloma after 1 to 3 prior treatments.
Influenza vaccine, adjuvanted (Fluad™)	The first seasonal influenza vaccine approved that contains an adjuvant. It is formulated for people 65 years of age or older.
Insulin glargine (Basaglar®)	Approved for glycemic control in patients with type 1 or type 2 diabetes mellitus
Ixazomib (Ninlaro®)	Approved, in combination with lenalidomide and dexamethasone, to treat multiple myeloma after at least 1 previous treatment
Lesinurad (Zurampic®)	Approved for use in combination with a xanthine oxidase inhibitor, to treat hyperuricemia associated with gout. Lesinurad should not be used as monotherapy.
Mepolizumab (Nucala®)	Approved for add-on maintenance treatment of severe asthma in patients 12 years of age or older with an eosinophilic phenotype. The injection is administered once monthly and is not indicated for other eosinophilic conditions, acute bronchospasm, or status asthmaticus.

Methylphenidate (QuilliChew ER™)	The first chewable extended-release form of methylphenidate approved to treat ADHD
Naloxone (Narcan®)	Approved for the emergency treatment of an opioid overdose, manifested by respiratory or CNS depression. The spray can be used in people of any age and delivers the same naloxone levels in the same time frame as the IM injection.
Osimertinib (Tagrisso™)	Approved to treat metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer in patients with disease progression during or after EGFR tyrosine kinase inhibitor therapy.
Recombinant von Willebrand factor (Vonvendi™)	Approved for as-needed treatment and control of bleeding episodes in adults with von Willebrand disease
Sebelipase alfa (Kanuma™)	The first treatment approved for patients older than 1 month who have lysosomal acid lipase deficiency.
Selexipag (Uptravi®)	Approved to treat patients with pulmonary arterial hypertension
Sugammadex (Bridion®)	Approved to reverse the effects of the neuromuscular-blocking drugs rocuronium and vecuronium.
Sumatriptan (Onzetra™ Xsail™)	Approved to treat acute migraine headaches; administered using the Xsail nosepiece, a breath-powered device that releases the sumatriptan powder into the nasal cavity.
Uridine triacetate (Vistogard®)	Approved for emergency treatment of fluorouracil or capecitabine toxicity, whether due to overdose or severe or life-threatening adverse reactions within 96 hours after administration.
<b>New FDA-approved Indications – Revised Monographs and Patient Medication Instructions</b>	
Carfilzomib (Kyprolis®)	Now approved in combination with dexamethasone for patients with relapsed or refractory multiple myeloma who have had between 1 and 3 lines of therapy
Dabigatran etexilate mesylate (Pradaxa®)	Now approved to prevent DVT and PE after hip replacement surgery
Eribulin mesylate (Halaven®)	Now approved to treat unresectable or metastatic liposarcoma in patients who have had prior chemotherapy with an anthracycline
Haemophilus b conjugate vaccine (Hiberix®)	Now indicated for active immunization in patients 6 weeks through 4 years of age. It was previously only indicated as a booster dose in patients 15 months through 4 years of age.
IncobotulinumtoxinA (Xeomin®)	Expanded the indication to include treatment of upper limb spasticity in adults
OnabotulinumtoxinA (Botox®)	Now indicated to treat lower limb spasticity in adults
Ofatumumab (Arzerra®)	Expanded the indication to include extended treatment in patients who have had partial or complete response to 2 or more lines of therapy for recurrent or progressive chronic lymphocytic leukemia
Secukinumab (Cosentyx®)	Now approved to treat adults with active ankylosing spondylitis and adults with psoriatic arthritis
<b>Drug Safety Updates</b>	
<b>Drug Safety – Revised Monographs and Patient Medication Instructions</b>	

Posaconazole	The US FDA warned that direct substitution between the 2 oral formulations of posaconazole has led to dosing errors causing hospitalization and death. Prescribers are urged to specify the dosage form, strength, and frequency on posaconazole prescriptions.
Proton pump inhibitors	The <i>JAMA Internal Medicine</i> published a report of a positive association between proton pump inhibitor (PPI) use and chronic kidney disease (CKD) in a population-based cohort. An analysis of data from more than 10,000 people found a 50% increased risk for CKD among PPI users compared with nonusers and 39% compared with histamine-2 receptor antagonist users. In previous studies, PPI use has been linked to acute interstitial nephritis.
<b>Other Significant Updates – Toxicology Content – New Monographs</b>	
	<p><b>Brexpiprazole (Rexulti®)</b></p> <ul style="list-style-type: none"> <li>• An atypical antipsychotic agent approved to treat schizophrenia and as adjunctive therapy for the treatment of major depressive disorder.</li> <li>• Overdose has not been reported; however, an extension of adverse effects seen at therapeutic doses should be anticipated.</li> <li>• Common adverse effects include increased weight, akathisia, and somnolence.</li> </ul>
	<p><b>Eluxadolone (Viberzi™)</b></p> <ul style="list-style-type: none"> <li>• Approved to treat patients with irritable bowel syndrome with diarrhea</li> <li>• Overdose data are limited and expected to be an extension of adverse events.</li> <li>• The most common adverse effects are constipation, nausea, and abdominal pain. Other potentially serious effects include: increased liver enzymes, viral gastroenteritis, gastroesophageal reflux disease, sedation, somnolence, asthma, bronchospasm, respiratory failure, wheezing, and pancreatitis.</li> </ul>
	<p><b>Sonidegib (Odomzo®)</b></p> <ul style="list-style-type: none"> <li>• Approved to treat adult patients with locally advanced basal cell carcinoma that has recurred following surgical or radiation therapy and in patients who are not candidates for surgery or radiation therapy</li> <li>• Overdose of sonidegib has not been reported; however, an extension of adverse effects seen at therapeutic doses should be anticipated.</li> <li>• The most common adverse effects include headache, abdominal pain, nausea, vomiting, diarrhea, dysgeusia, decreased appetite, decreased weight, muscle spasm, myalgia, musculoskeletal pain, fatigue, pruritus, alopecia, anemia, and lymphopenia. Effects appear to be dose-dependent.</li> </ul>
<b>Other Significant Updates – CareNotes Patient Education</b>	
<i>Following the November 1<sup>st</sup> 2015 quarterly release, CareNotes has transitioned to a monthly release in order to provide this content and to respond to customer requests in a more timely manner.</i>	
41 New CareNotes	<p>New patient instructions cover a variety of topics including:</p> <ul style="list-style-type: none"> <li>• Cardiac thrombolysis, COPD, gunshot wounds, physical therapy for ACL injury, rectal prolapse, and stroke</li> </ul>

	<ul style="list-style-type: none"> <li>• There are also 111 new ambulatory documents for the outpatient setting.</li> </ul>
80 Revised CareNotes	<p>Topics have been revised to incorporate new evidence and new and updated clinical guideline recommendations including:</p> <ul style="list-style-type: none"> <li>• Influenza Vaccine, Influenza, and Influenza in Children topics to include the most recent influenza vaccine guideline that came out in August 2015 from the CDC. This guideline is for the 2015-2016 flu season.</li> <li>• Enhancing the Ambulatory topics to provide a more robust repository with a focus on creating sub-topics or associated topics that are shorter but deal with one aspect of care. For example, there is an Esophagectomy CareNote and “After Esophagectomy” title and “Before Esophagectomy” titles were created to deal with the preparation for the procedure and the discharge care after the procedure.</li> </ul>
<b>Neofax</b>	
<b>New Monographs and Calculators</b>	Asfotase alfa, cysteamine, uridine triacetate.
<b>Revised Monographs</b>	<p><b>Content updates:</b> Acetaminophen, adenosine, amiodarone, atropine, bosentan, bumetanide, caffeine citrate, calcium chloride 10%, cefepime, chlorothiazide, cimetidine, dexamethasone, dextrose, didanosine, digoxin, dobutamine, dopamine, emtricitabine, epinephrine (adrenaline), famotidine, furosemide, hyaluronidase, hydrochlorothiazide, hydrocortisone, ibuprofen, lamivudine, levetiracetam, lidocaine - antiarrhythmic, lopinavir/ritonavir, magnesium sulfate, metoclopramide, milrinone, naloxone, nevirapine, nitric oxide, penicillin G benzathine, procainamide, propranolol, ranitidine, sildenafil, sodium bicarbonate, sodium chloride (0.9%), sodium nitroprusside, sodium polystyrene sulfonate, spironolactone, zidovudine.</p> <p><b>Dose changes:</b> Cefepime, sildenafil, zidovudine.</p>
<b>New Enteral Formulas</b>	Enfamil® Premature 30, Enfamil® Premature High Protein 24, Enfamil® Premature With Iron 20, Enfamil® Premature With Iron 24.
<b>Revised Enteral Formulas</b>	Enfamil® 24, Enfamil® Premature Low Iron 20, Enfamil® Premature Low Iron 24
<b>Pediatrics</b>	
<b>New Monographs and Calculators</b>	Abacavir/lamivudine, aprepitant, aripiprazole, asfotase alfa, cysteamine, elvitegravir/cobicistat/emtricitabine/tenofovir, mepolizumab, mycophenolic acid, quetiapine, rilpivirine, tiotropium, uridine triacetate.
<b>Revised Monographs</b>	<p><b>Content updates:</b> Abacavir, acetaminophen, adenosine, amiodarone, amlodipine, amphetamine, atazanavir, atropine, bosentan, bumetanide, calcium chloride 10%, cefepime, cephalexin, chlorothiazide, cimetidine, ciprofloxacin, darunavir, deferasirox, dexamethasone, dextrose, didanosine, digoxin, diltiazem, dobutamine, dolutegravir, dopamine, eculizumab, efavirenz, emtricitabine, epinephrine (adrenaline), epoprostenol, etomidate, etravirine, famotidine, fosamprenavir, furosemide, human papillomavirus 9-valent vaccine, recombinant, hyaluronidase, hydrochlorothiazide, hydrocortisone, hypertonic saline, ibuprofen, iloprost, lamivudine, levetiracetam, lidocaine - antiarrhythmic, lopinavir/ritonavir, magnesium</p>

	<p>sulfate, methylphenidate, metoclopramide, milrinone, montelukast, naloxone, nevirapine, nifedipine, nitric oxide, olanzapine, omalizumab, oxcarbazepine, penicillin G benzathine, penicillin G benzathine/penicillin G procaine, procainamide, propranolol, raltegravir, ranitidine, ritonavir, rosuvastatin, sildenafil, sodium bicarbonate, sodium nitroprusside, sodium polystyrene sulfonate, spironolactone, taliglucerase alfa, tenofovir, warfarin, zidovudine.</p> <p><b>Dose changes:</b> Cefepime, nevirapine, propranolol, taliglucerase alfa, zidovudine, amphetamine, atazanavir, cephalexin, human papillomavirus 9-valent vaccine (recombinant), ibuprofen, lamivudine, ritonavir, rosuvastatin, sildenafil, zidovudine.</p>
<b>Enteral Formula New</b>	Enfamil® Premature 30, Enfamil® Premature High Protein 24, Enfamil® Premature With Iron 20, Enfamil® Premature With Iron 24.
<b>Revised Enteral Formulas</b>	Enfamil® 24, Enfamil® Premature Low Iron 20, Enfamil® Premature Low Iron 24