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Truven Health Analytics™ Micromedex® Solutions Clinical Content Updates

May, June and July 2016 Selected Content Updates

Selected New Drug Approvals	
FDA Approvals – New Monographs and Patient Medication Instructions	
Topic / Title	**Implication**
Aminolevulinic acid (Ameluz®)	Approved for use with the BF-RhodoLED® photodynamic therapy lamp to treat mild to moderate actinic keratosis of the face and scalp
Antihemophilic factor (recombinant), single chain (Afstyla®)	The first single-chain hemophilia A product approved to prevent and treat bleeding episodes in adult and pediatric patients
Atezolizumab (Tecentriq™)	The first PD-L1 inhibitor approved to treat the most common type of bladder cancer, urothelial carcinoma
Buprenorphine (Probuphine®)	Approved the first subdermal implant for opioid dependence. The 6-month implant is placed in the upper arm
Cholera vaccine, live (Vaxchora™)	The first and only FDA-approved oral cholera vaccine to provide active immunization against disease caused by *Vibrio cholera* serogroup O1 in adults 18 through 64 years of age traveling to cholera-affected areas
Calcifediol (Rayaldee®)	Approved the first treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels of < 30 nanograms/mL
Daclizumab (Zinbryta™)	Approved to treat relapsing multiple sclerosis in adults as a long-lasting injection that is self-administered monthly

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Dasabuvir/ombitasvir/paritaprevir/ritonavir (Viekira XR™)	Approved this single fixed-dose oral extended-release tablet for genotype 1 chronic hepatitis C in adults. This combination is already approved as the Viekira Pak® kit which includes an ombitasvir/paritaprevir/ritonavir fixed-dose tablet and a separate dasabuvir tablet.
Dronabinol (Syndros™)	Approved this pharmaceutical formulation of tetrahydrocannabinol, as the first oral solution for treating weight loss-associated anorexia in patients with AIDS and for treating chemotherapy-induced nausea and vomiting in patients with cancer
Gallium Ga 68 dotatate (Netspot™)	Approved under priority review and granted orphan drug status for use with positron emission tomography imaging to detect somatostatin receptor positive neuroendocrine tumors
Lifitegrast (Xiidra™)	Approved the only prescription eye drop indicated to treat signs and symptoms of dry eye disease
Linagliptin/metformin (Jentadueto® XR)	Approved for once-daily treatment of type 2 diabetes in adults
Lisinopril (Qbrelis™)	Approved as the first lisinopril oral solution to treat hypertension in adult patients and pediatric patients 6 years of age and older
Lixisenatide (Adlyxin™)	Approved to improve glycemic control in adults with type 2 diabetes. Lixisenatide is approved in more than 60 countries under the name, Lyxumia®.
Lorcaserin hydrochloride (BELVIQ XR®)	Approved a new extended-release dose form taken once daily for chronic weight management in adults
Methylnaltrexone bromide (Relistor®)	Approved as oral tablets to treat opioid-induced constipation in adults with chronic noncancer pain. The drug was already approved as a subQ injection.
Nebivolol/valsartan (Byvalson™)	The first combination angiotensin II receptor blocker and beta blocker approved to treat hypertension.
Nitroglycerin (Gonitro™)	Approved the first sublingual powder in single-use packets to prevent and treat angina pectoris caused by coronary artery disease

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Obeticholic acid (Ocaliva™)	Approved alone or with ursodeoxycholic acid (UDCA) to treat primary biliary cholangitis in adults providing an alternative treatment option for those who have not responded to or are intolerant of UDCA
Perampanel (Fycompa®)	Approved this oral suspension to treat seizures in patients 12 years of age or older and is an interchangeable bioequivalent to the tablet form
Sofosbuvir/velpatasvir (Epclusa®)	Approved the first treatment for adults with any genotype of chronic hepatitis C virus
Tetracaine hydrochloride/oxymetazoline hydrochloride (Kovanaze™)	Approved the first dental anesthetic product administered via nasal route
EMA Approvals (not already approved by FDA – New Monographs	
Topic / Title	**Implication**
Migalastat (Galafold)	Indicated for long-term treatment of adults and pediatric patients 16 years of age or older with a confirmed diagnosis of Fabry disease and who have an amenable mutation
Opicapone (Ongentys)	Indicated as adjunctive therapy to levodopa/DOPA decarboxylase inhibitors combinations in adult patients with Parkinson disease and end-of-dose motor fluctuations
Saxagliptin hydrochloride/dapagliflozin propanediol (Qtern)	Indicated to improve glycemic control in adult patients 18 years of age or older with type 2 diabetes mellitus
New FDA-approved Indications – Revised Monographs and Patient Medication Instructions	
Adalimumab (Humira®)	Expanded the approval to include treatment of noninfectious intermediate, posterior, and panuveitis making it the first FDA-approved noncorticosteroid therapy for this indication
Alpha proteinase inhibitor human (Glassia®)	Expanded the approval to allow adult patients with emphysema due to severe alpha-1 antitrypsin deficiency to self-infuse at home after proper training

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C1 esterase inhibitor, human (Berinert®)	Now approved as the first and only treatment for pediatric patients under 12 years of age with hereditary angioedema and also approved an updated indication for geriatric patients, expanding its use to include all age groups
Canagliflozin/metformin (Invokamet®)	Now approved as first-line treatment of adults with type 2 diabetes mellitus. Invokamet® was previously approved for patients who were already taking the two drugs separately.
Ceftaroline fosamil (Teflaro®)	Expanded the indication to include treatment of pediatric patients 2 months of age or older with acute bacterial skin and skin structure infections
Evolocumab (Repatha®)	Now approved with the Pushtronex™ system, an on-body infusor with a prefilled cartridge for once monthly subQ administration
Ibrutinib (Imbruvica®)	Expanded the indication for the oral capsules to include treatment of patients with chronic lymphocytic leukemia or with small lymphocytic lymphoma
Lenvatinib (Lenvima®)	Expanded the indication to include treatment of advanced renal cell carcinoma after antiangiogenic therapy in combination with everolimus
Nivolumab (Opdivo®)	Granted accelerated approval to treat classical Hodgkin lymphoma following disease relapse or progression after autologous hematopoietic stem cell transplantation and post-transplantation
Omalizumab (Xolair®)	Now approved for use in children 6 years or older who have moderate to severe persistent asthma. It was previously approved for this indication in children 12 years or older
Pneumococcal 13-valent conjugate vaccine, diphtheria conjugate (Prevnar 13®)	Expanded the indication to include adults 18 through 49 years of age for the prevention of pneumococcal pneumonia and invasive disease caused by 13 *Streptococcus pneumonia* strain
Telavancin (Vibativ®)	Now approved to treat concomitant bacteremia in patients with complicated skin and skin structure infections or hospital-acquired and ventilator-associated bacterial pneumonia
Drug Safety Updates – Revised Monographs and Patient Medication Instructions	

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Topic / Title	Implication
Aripiprazole (Abilify®, Abilify Maintena®, Aristada™)	The US FDA announced that compulsive or uncontrollable urges to gamble, binge eat, shop, or have sex have been reported with the antipsychotic drug, aripiprazole. These urges stopped upon dose reduction or therapy discontinuation.
Aspirin-containing antacids	The US FDA announced that there is a risk of serious bleeding with use of over-the-counter aspirin-containing antacids. The labels have a warning about this bleeding risk; however, the FDA continues to receive reports of serious bleeding events with use of these products.
Canagliflozin products (Invokana®, Invokamet®)	The US FDA issued an alert about an increase in leg and foot amputations in patients treated with canagliflozin products. The FDA is currently investigating whether canagliflozin use contributes to an increased risk of amputation.
Canagliflozin products (Invokana®, Invokamet®) and Dapagliflozin products (Farxiga® and Xigduo® XR)	The US FDA strengthened the acute kidney injury warning for these type 2 diabetes drug products due to numerous cases (some requiring hospitalization and dialysis) that have been reported to the FDA.
Carmustine (BiCNU)	The US FDA announced that a counterfeit version of BiCNU has been detected in some foreign countries. Healthcare professionals are encouraged to inspect the vial for authenticity, to purchase drug products only from legitimate suppliers, and to report sales solicitation of suspect drug products to the FDA.
Fluoroquinolone antibiotics	The US FDA announced that it is requiring updates to all fluoroquinolone antibiotic drug labels due to disabling and potentially permanent serious side effects. Fluoroquinolones should be reserved for those who do not have alternative treatment options.
Loperamide (Imodium®)	The US FDA warned that higher than recommended doses of Imodium® (loperamide), an oral over-the-counter and prescription diarrhea medicine, can cause serious cardiac events leading to death, including QT prolongation, torsades de pointes, cardiac arrest, and syncope.

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Olanzapine (Zyprexa®, Zyprexa® Zydis®, Zyprexa® Relprevv™, Symbyax®, generics)	The US FDA announced that Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with olanzapine use at doses as low as 5 mg per day. If DRESS is suspected, olanzapine should be discontinued immediately.
Sumatriptan (Zecuity®)	The US FDA announced that the Zecuity® iontophoretic transdermal patch may increase the risk for serious burns and potentially permanent scarring.
Vortioxetine (Trintellix®)	The US FDA required a name change for this drug from Brintellix® to Trintellix® in order to prevent name confusion with the antiplatelet drug, Brilinta® (ticagrelor).
Other Significant Updates – Drug	
Topic / Title	**Implication**
Adapalene (Differin®)	Approved as the first in the retinoid class to be available over-the-counter treatment of acne in people 12 years of age or older after being prescription only.
Influenza virus vaccine, live (Flumist® Quadrivalent)	The CDC's Advisory Committee on Immunization Practices announced that the live attenuated influenza vaccine nasal spray should not be used during the 2016-2017 flu season. Data from last year's vaccine indicated that no protective benefit could be measured.
Other Significant Updates – CareNotes	
Topic / Title	**Implication**
50+ New CareNotes	New patient instructions cover a variety of topics including: • Zika Virus • Heart Failure • Pancreatic Cancer And, the CareNotes Team continues to update ICD10 codes across content.

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Other Significant Updates – Toxicology Content

Dengue Fever
 	
• Dengue is a mosquito-borne viral illness of the flavivirus genus that belongs to the flaviviridae family
• Primarily transmitted to humans through the bite of an infected female mosquito of the Aedes aegypti and Aedes albopictus species.
• An infected mosquito can transmit the virus after an incubation period of 3 to 14 days.
• Up to 50% of persons infected with dengue are asymptomatic.
• Symptomatic patients may present with undifferentiated fever, dengue fever with or without hemorrhage, or dengue hemorrhagic fever, or dengue shock syndrome
• Treatment is symptomatic and supportive.
  ○ There is no specific antiviral therapy for dengue virus infection.
  ○ Monitor during the 2- to 7-day febrile phase and the 1- to 2-day critical phase.

Eslicarbazepine (Aptiom®) • Indicated to treat partial-onset seizures in adults. as either monotherapy or as adjunctive therapy • Overdose data are limited. • The most commonly reported adverse effects include dizziness, somnolence, nausea, vomiting, headache, diplopia, fatigue, vertigo, ataxia, tremor, and blurred vision.
Brivaracetam (Briviact®) • Indicated for the adjunctive treatment of partial-onset seizures in patients with epilepsy • Overdose effects are anticipated to be an extension of adverse effects following therapeutic administration, including somnolence/sedation, dizziness, vertigo, fatigue, nausea, diplopia, anxiety, and bradycardia.
Lesinurad (Zurampic®) • A URAT1 inhibitor indicated for use in combination with a xanthine oxidase inhibitor to treat hyperuricemia associated with gout • Not recommended for use as a monotherapy to avoid the risk of acute renal failure. • Exposure is uncommon and overdose data are limited. • Clinical events are anticipated to be an extension of adverse events reported with lesinurad therapy, including headache, increased serum creatinine, influenza and gastroesophageal reflux.

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2nd Quarter 2016 Selected NeoFax and Pediatrics Content Updates	
NeoFax	
New Monographs and Calculators	Obiltoxaximab
Revised Monographs	Albuterol, ampicillin, azithromycin, buprenorphine, caspofungin, cefazolin, cefotaxime, ceftazidime, ceftriaxone, chloramphenicol, clindamycin, dexamethasone, dexmedetomidine, didanosine, dornase alfa, emtricitabine, epinephrine (adrenaline), epoetin alfa, erythromycin, fat emulsion, ferrous sulfate, hydrochlorothiazide, ibuprofen, isoproterenol, lamivudine, levetiracetam, lidocaine - CNS, linezolid, lopinavir/ritonavir, lorazepam, meropenem, mupirocin, nafcillin, neostigmine, nevirapine, oxacillin, palivizumab, penicillin g, phenytoin, piperacillin/tazobactam, poractant alfa, propranolol, ranitidine, rifampin, tobramycin, vancomycin, zidovudine
Dose Changes	Epinephrine (adrenaline), lamivudine, meropenem, nevirapine
Pediatrics	
New Monographs and Calculators	Abatacept, anakinra, antihemophilic factor VIII (recombinant) pegylated, ceftaroline fosamil, ciprofloxacin/fluocinolone, emtricitabine/tenofovir alafenamide, emtricitabine/tenofovir disoproxil fumarate, factor IX albumin fusion protein recombinant, insulin glargine, recombinant, obiltoxaximab, riboflavin 5-phosphate, tocilizumab.
Revised Monographs	Abacavir, abacavir/lamivudine, adalimumab, albuterol, amoxicillin/clavulanate, amphetamine, ampicillin, aripiprazole, atazanavir, azithromycin, beclomethasone, budesonide, budesonide/formoterol, buprenorphine, canakinumab, caspofungin, cefazolin, cefotaxime, ceftazidime, ceftriaxone, cephalexin, chloramphenicol, ciclesonide, ciprofloxacin, clindamycin, clobazam, cyclosporine, darunavir, defibrotide, dexamethasone, dexmedetomidine, diclofenac, dicloxacillin, didanosine, diltiazem, dolutegravir, dornase alfa, doxycycline, efavirenz, elvitegravir/cobicistat/emtricitabine/tenofovir, emtricitabine, emtricitabine/rilpivirine/tenofovir alafenamide, emtricitabine/rilpivirine/tenofovir disoproxil, epinephrine (adrenaline), epoetin alfa, erythromycin, etanercept, ethosuximide, etravirine, factor X human, ferrous sulfate, flunisolide, fluticasone, fluticasone/salmeterol, formoterol, fosamprenavir, gabapentin, hydrochlorothiazide, hypertonic saline,

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	ibuprofen, infliximab, influenza virus vaccine, ivacaftor, ketorolac, lamivudine, levetiracetam, levofloxacin, lidocaine - CNS, linezolid, lopinavir/ritonavir, lorazepam, lumacaftor/ivacaftor, meningococcal vaccine (group a, c, y, and w-135), meningococcal/Hib conjugate combination vaccine, meropenem, metformin, methotrexate, methylprednisolone, mometasone, montelukast, moxifloxacin, mupirocin, nafcillin, neostigmine, nevirapine, olanzapine, oxacillin, palivizumab, penicillin g, perampanel, phenytoin, piperacillin/tazobactam, prednisolone, prednisone, propranolol, raltegravir, ranitidine, rifampin, rilpivirine, ritonavir, rosuvastatin, salmeterol, tacrolimus, tenofovir disoproxil fumarate, tobramycin, trimethoprim/sulfamethoxazole, vancomycin, vigabatrin, zafirlukast, zidovudine, zileuton, zonisamide.
Dose Changes	Abacavir, amphetamine, atazanavir, budesonide, darunavir, dolutegravir, doxycycline, emtricitabine, epinephrine (adrenaline), lamivudine, lopinavir/ritonavir, lorazepam, raltegravir, rifampin, ritonavir, rosuvastatin, tenofovir disoproxil fumarate, tobramycin, zidovudine.

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