

**Selected Content Updates for Customer Newsletter and Content Updates Link  
August – September – October 2016**

August – September - October 2016 Selected Content Updates	
Topic/Title	Implication
<b>Drug Content</b>	
<b>New FDA Approvals</b>	
Adalimumab-atto (Amjevita™)	First adalimumab biosimilar approved by the FDA to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, Crohn disease and ulcerative colitis
Bezlotoxumab (Zinplava™)	Indicated to reduce the recurrence of <i>Clostridium difficile</i> infection (CDI) in adult patients who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence
Canagliflozin/metformin in hydrochloride (Invokamet® XR)	Extended-release tablets approved for first-line treatment as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes
Carbamazepine (Carnexiv™)	First available carbamazepine IV formulation approved short-term replacement therapy for oral carbamazepine in adults with certain types of seizures. The IV formulation makes it possible for patients to receive continuous therapy even when oral administration is not possible.
Etanercept-szsz (Erelzi™)	Etanercept biosimilar approved to treat rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis. Erelzi™ is the second biosimilar approved by the FDA allowing broader access to the drug.
Eteplirsen (Exondys 51™)	First drug approved to treat Duchenne muscular dystrophy in patients with a confirmed mutation of the dystrophin gene amenable to exon 51 skipping
Immune globulin (Cuvitru™)	Once monthly subQ injection approved as replacement therapy for primary humoral immunodeficiency in adult and pediatric patients 2 years and older and may result in fewer infusions and
Influenza virus vaccine recombinant (Flublok® Quadrivalent)	First and only high antigen content quadrivalent flu vaccine approved to protect against 4 strains of influenza, three of the same strains found in trivalent Flublok® plus an additional B strain
Mebendazole (Vermox™)	Approved to treat GI infections caused by <i>Ascaris lumbricoides</i> (roundworm) and <i>Trichuris trichiura</i> (whipworm) in patients 1 year of age and older
Olaratumab (Lartruvo™)	Indicated in combination with doxorubicin to treat adults with soft tissue sarcoma
Oxycodone hydrochloride/naltrex	ER tablets with abuse deterrent properties indicated to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate

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one hydrochloride (Troxyca® ER)	

**New FDA-approved indications**

AbobotulinumtoxinA (Dysport®)	Expanded indication to include pediatric patients 2 years and older with lower limb spasticity; first and only FDA-approved botulinum toxin for this pediatric indication
Atezolizumab (Tecentriq®)	Expanded indication to include patients with metastatic non-small cell lung cancer whose disease progressed during or following platinum-containing chemotherapy
Blinatumomab (Blinicyto®)	Expanded indication to include pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.
Canakinumab (Ilaris®)	Now approved to treat tumor necrosis factor receptor associated periodic syndrome, hyperimmunoglobulin D syndrome/mevalonate kinase deficiency, and familial Mediterranean fever in adult and pediatric patients
Ivacaftor/lumacaftor (Orkambi®)	Expanded the indication to include pediatric patients 6 years of age or older; was previously approved for those 12 years or older
Pembrolizumab (Keytruda®)	Now indicated to treat recurrent or metastatic head and neck squamous cell carcinoma with disease progression during or following platinum-containing chemotherapy and to treat metastatic non-small cell lung cancer in patients whose tumors have high programmed death ligand 1 expression as determined by an FDA-approved test
Ustekinumab (Stelara®)	Now indicated to treat moderately to severely active Crohn disease in adults

**Drug Safety**

Direct-acting hepatitis C antiviral drugs	The US FDA warned about the risk of hepatitis B virus (HBV) reactivation in patients who are currently or have previously been infected with HBV and are being treated with certain direct-acting antiviral medicines for hepatitis C virus
Opioids and benzodiazepines	The US FDA announced serious safety concerns with the combined use of prescription opioid pain or cough medicines and benzodiazepines or other CNS depressants. Combination therapy has resulted in serious side effects, including slowed or difficult breathing and deaths. Labeling changes are required in the form of new Boxed Warnings.
Testosterone	US FDA approved labeling changes for all prescription testosterone products to include new safety information regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids

**Other significant updates**

Fluticasone furoate (Flonase® Sensimist™)	Now approved over-the-counter to treat symptoms associated with seasonal and perennial allergic rhinitis in adults and children 2 years of age or older. Fluticasone furoate was previously available only by prescription under the brand name, Veramyst®
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Human papillomavirus 9-valent vaccine, recombinant (Gardasil® 9)	New 2-dose regimen approved for adolescents 9 to 14 years of age; second dose can be administered 6 to 12 months after the initial dose
Nivolumab (Opdivo®)	Approved recommended dosage regimens were modified from 3 mg/kg every 2 weeks to 240 mg every 2 weeks until disease progression or intolerable toxicity occur based on analyses of population pharmacokinetics and dose/exposure-response.
Oseltamivir phosphate (generic for Tamiflu®)	Approved the first generic version of Tamiflu® (oseltamivir phosphate) oral capsules to treat influenza A and B in patients 2 weeks of age or older and to prevent flu in patients 1 year of age or older.
Pancrelipase (Pertzye®)	A 4000-USP lipase units capsule strength now approved for specifically for infants up to 12 months allowing more improved dosing options from infancy through adulthood

Care Notes	
Topic/Title	Implication
30+ New CareNotes	<p>New patient instructions cover a variety of topics including:</p> <ul style="list-style-type: none"> <li>• Hazardous Medicine Safety</li> <li>• Post Concussion Syndrome in Children</li> <li>• Wellness Visit for Adults</li> </ul> <p>The CareNotes Team has been focusing on building up pediatric offerings, including disease titles and procedure titles.</p> <p>The following is a complete list of new documents: atypical facial pain, biliary dyskinesia, brain tumors, brain tumors in children, chronic inflammatory demyelinating polyneuropathy, chronic traumatic encephalopathy contracture, early postoperative or post injury shoulder exercises, exercise safety, exercises for internal and external shoulder rotation, exercises for shoulder abduction and adduction, exercises for shoulder flexion and extension, endometrial ablation, fine needle aspiration biopsy, fistulogram, glomerular filtration rate test, hazardous medicine safety, home apnea monitor, keratosis pilaris, lattice degeneration, lichen sclerosus, lichen striatus in children, liver or spleen laceration, memory loss in older adults, parathyroid adenoma, post-concussion syndrome in children, retinal round hole, safe sex practices for adolescents, Sjogren syndrome, slipped capital femoral epiphysis, soft tissue foreign body in children, soft tissue mass, stapled hemorrhoidopexy, surgery for retinal detachment, tachycardia, wellness visit for adults</p>
Disease Content	
Topic/Title	Implication
New guidelines	<ul style="list-style-type: none"> <li>• Suspected Female-to-Male Sexual Transmission of Zika Virus</li> </ul>

	<ul style="list-style-type: none"> <li>• Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products</li> <li>•</li> </ul>
Revised guidelines	<ul style="list-style-type: none"> <li>• Interim Guidance for Prevention of Sexual Transmission of Zika Virus — United States, July 2016</li> <li>• Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure — United States, July 2016</li> <li>• Interim Guidance for the Evaluation and Management of Infants with Possible Congenital Zika Virus Infection</li> <li>• Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components</li> <li>• Surviving Sepsis Campaign Updated Bundles in Response to New Evidence</li> <li>• Interim Guidance for Preconception Counseling and Prevention of Sexual Transmission of Zika Virus for Persons with Possible Zika Virus Exposure — United States, September 2016</li> </ul>

Toxicology Content	
Topic/Title	Implication
New monographs	<b>Pimavanserin (Nuplazid™)</b> <ul style="list-style-type: none"> <li>• Indicated to treat hallucinations and delusions associated with Parkinson disease psychosis</li> <li>• May be mediated through inverse agonist and antagonist activity at serotonin 5-HT(2A) and serotonin 5-HT(2C) receptors</li> <li>• Overdose data are limited. Nausea and vomiting have been reported. In studies, QTc interval prolongation occurred at twice the therapeutic dose.</li> <li>• Common adverse events: peripheral edema and confusion. Other events include nausea, gait disturbance, and hallucinations.</li> <li>• Symptomatic and supportive care. Monitor for QT interval prolongation following exposure and/or in patients receiving concomitant therapy that can prolong the QT interval.</li> </ul>
	<b>Reslizumab (Cinqair®)</b> <ul style="list-style-type: none"> <li>• Indicated for add-on maintenance treatment of adults with severe asthma and an eosinophilic phenotype</li> <li>• Not indicated for acute bronchospasm or status asthmaticus.</li> <li>• Blocks binding of IL-5 to the surface of eosinophils, thus reducing the production and survival of the eosinophil.</li> <li>• No reports of overdose.</li> <li>• Common adverse effects: oropharyngeal pain. Other events include anaphylaxis, CPK elevations, musculoskeletal pain or spasms.</li> <li>• Symptomatic and supportive care. Treat acute allergic reactions with oxygen, bronchodilators, diphenhydramine, corticosteroids, vasopressors and epinephrine as required</li> </ul>
	<b>Tofacitinib (Xeljanz®)</b> <ul style="list-style-type: none"> <li>• Indicated for use in combination with a xanthine oxidase inhibitor to treat hyperuricemia associated with gout</li> </ul>

	<ul style="list-style-type: none"> <li>• Not recommended for use as a monotherapy to avoid the risk of acute renal failure.</li> <li>• Exposure is uncommon and overdose data are limited.</li> <li>• Clinical events are anticipated to be an extension of adverse events reported with lesinurad therapy, including headache, increased serum creatinine, influenza and gastroesophageal reflux.</li> </ul>
	<p><b>Venetoclax (Venclexta™)</b></p> <ul style="list-style-type: none"> <li>• Indicated to treat patients with chronic lymphocytic leukemia with 17p deletion, who have received at least 1 prior therapy.</li> <li>• Restores apoptosis by binding to the beta cell lymphoma-2 protein in chronic lymphocytic leukemia cells.</li> <li>• No reports of overdose.</li> <li>• Common adverse effects: neutropenia, diarrhea, nausea, anemia, upper respiratory tract infection, thrombocytopenia and fatigue. Tumor lysis syndrome (TLS) occurred during initiation of therapy in phase I trials</li> <li>• Symptomatic and supportive care. Monitor patients closely for evidence of TLS and initiate aggressive IV therapy and correct electrolytes in patients with evidence of TLS. Consider administering colony stimulating factors. Transfusion of platelets and/or packed red cells may be needed for severe thrombocytopenia, anemia, or hemorrhage.</li> </ul>

<b>NeoFax and Pediatrics Content for 3<sup>rd</sup> Quarter</b>	
<b>NeoFax</b>	
<b>New Monographs and Calculators</b>	Antihemophilic factor (recombinant) single chain, methylene blue, raxibacumab
<b>Revised Monographs</b>	Acetaminophen, acetylcysteine, amiodarone, atropine, azithromycin, bosentan, buprenorphine, cefepime, ceftazidime, clopidogrel, colistin, dexmedetomidine, dextrose, dornase alfa, enalapril maleate, Enfamil® human milk fortifier powder, epinephrine (adrenaline), fat emulsion, fentanyl, fluconazole, fosphenytoin, hydrocortisone, ibuprofen, imipenem/cilastatin, immune globulin (human), indomethacin, lamivudine, lopinavir/ritonavir, lorazepam, magnesium sulfate, meropenem, methadone, midazolam, nicardipine, nitric oxide, obiltoximab, oseltamivir, palivizumab, pentobarbital, phenytoin, piperacillin, piperacillin/tazobactam, Prolact+ H(2) MF® human milk fortifier, propranolol, remifentanyl, Similac® human milk fortifier powder, sodium bicarbonate, sotalol, ticarcillin/clavulanate, topiramate, vancomycin.
<b>Dose changes</b>	Acetaminophen and atropine
<b>Pediatrics</b>	
<b>New Monographs and Calculators</b>	Adalimumab-atto, antihemophilic factor (recombinant) single chain, benazepril, dextansoprazole, fosinopril, infliximab-dyyb, leflunomide, methylene blue, raxibacumab, riloncept.
<b>Revised Monographs</b>	Acetaminophen, acetaminophen/codeine, acetylcysteine, amiodarone, amoxicillin/clavulanate, aripiprazole, asenapine, atazanavir, atropine, azithromycin, baclofen, bosentan, budesonide, buprenorphine, C1 esterase inhibitor, human, canakinumab, cefepime, ceftaroline fosamil, ceftazidime, clobazam, clonazepam, clopidogrel, colistin, daptomycin, darunavir, deferasirox, desmopressin, dexmedetomidine, dextrose, diazepam, dornase alfa, efavirenz, elvitegravir/cobicistat/emtricitabine/tenofovir, enalapril maleate,

	<p>Enfamil® human milk fortifier powder, epinephrine (adrenaline), ertapenem, evolocumab, fat emulsion, fentanyl, fluconazole, fluticasone, fosamprenavir, fosphenytoin, glycerol phenylbutyrate, guanfacine, hydrocodone/acetaminophen, hydrocodone/ibuprofen, hydrocortisone, hydromorphone, ibuprofen, imipenem/cilastatin, immune globulin (human), indomethacin, influenza virus vaccine, lamivudine, lisinopril, lopinavir/ritonavir, lorazepam, lumacaftor/ivacaftor, magnesium sulfate, meropenem, methadone, midazolam, moxifloxacin, nifedipine, nitric oxide, nitroglycerin, obiltoxaximab, olanzapine, omalizumab, oseltamivir, oxycodone, oxycodone/acetaminophen, oxycodone/ibuprofen, palivizumab, pentobarbital, phenytoin, piperacillin, piperacillin/tazobactam, prednisone, Prolact+ H(2) MF® human milk fortifier, propranolol, quetiapine, remifentanyl, riboflavin 5-phosphate, risperidone, ritonavir, ropivacaine, Similac® human milk fortifier powder, simvastatin, sodium bicarbonate, somatropin, sotalol, sumatriptan/naproxen, ticarcillin/clavulanate, topiramate, tramadol, vancomycin, vasopressin, verapamil, voriconazole, warfarin.</p>
<b>Dose changes</b>	<p>Abatacept, acetaminophen, budesonide, C1 esterase inhibitor, human, canakinumab, epinephrine (adrenaline), fluticasone, fosphenytoin, fosphenytoin, glycerol phenylbutyrate, immune globulin (human), lumacaftor/ivacaftor, omalizumab, phenytoin, vasopressin, vasopressin.</p>
<b><i>NeoFax and/or Pediatrics</i></b>	
<b>Enteral Formula updates</b>	<p>All enteral formulas have been reviewed and updated per manufacturers' product information.</p>