

New Drugs for 2009 (January – July 2009)

Generic Name (Brand Name)	Dosage Form	Indication	Significant Adverse Effects	Notes
New Molecular Entities				
Prasugrel (Effient)	Tablet (5 mg, 10 mg)	Reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome	<ul style="list-style-type: none"> Bleeding 	<ul style="list-style-type: none"> REMS program Black box warning—risk of bleeding, do not use with history of stroke/TIA, CI if ≥75 years, discontinue 7 days prior to surgery
Dronaderone (Multaq)	Tablet (400 mg)	Reduce the risk of hospitalization in patients with paroxysmal or persistent atrial fibrillation or atrial flutter	<ul style="list-style-type: none"> Arrhythmia GI upset 	<ul style="list-style-type: none"> REMS program Black box warning—increased mortality in patients with severe heart failure Potential for many drug interactions
Ferumoxytol (Feraheme)	Vial for injection (30 mg/ml)	Treatment of iron deficiency anemia in adult patients with chronic kidney disease	<ul style="list-style-type: none"> Hypotension Dizziness 	<ul style="list-style-type: none"> Give 2 doses separated by 3-8 days May interfere with MRI for up to 3 months
Artemether/lumefantrine (Coartem)	Tablet (20 mg)	Treatment of acute, uncomplicated malaria	<ul style="list-style-type: none"> Arrhythmia 	<ul style="list-style-type: none"> Take with food for maximal absorption
Everolimus (Afinitor)	Tablet (5 mg, 10 mg)	Treatment of advanced renal cell carcinoma	<ul style="list-style-type: none"> Bone marrow suppression Risk of infection Mouth ulceration 	<ul style="list-style-type: none"> Do not chew or crush
Tolvaptan (Samsca)	Tablet (15 mg, 30 mg)	Treatment of clinically significant hypervolemic and euvolemic hyponatremia	<ul style="list-style-type: none"> Thirst, dry mouth Frequent urination 	<ul style="list-style-type: none"> Black box warning—initiate and re-initiate in a hospital Do not use if patient cannot sense and respond to thirst Use only in patients who make urine Potential for many drug interactions
Milnacipran (Savella)	Tablet (12.5 mg, 25 mg, 50 mg, 100 mg)	Management of fibromyalgia	<ul style="list-style-type: none"> GI upset 	<ul style="list-style-type: none"> REMS program Black box warning—suicide

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Febuxostat (Uloric)	Tablet (40 mg, 80 mg)	Chronic management of hyperuricemia in patients with gout	<ul style="list-style-type: none"> Increased liver enzymes 	<ul style="list-style-type: none"> May cause gout flare May increase risk of stroke/heart attack
Biologics				
Antithrombin (ATryn)	Vial for reconstitution (1750 IU per vial)	Prevention of peri-operative and peri-partum thromboembolic events in patients with hereditary antithrombin deficiency	<ul style="list-style-type: none"> Bleeding Infusion reactions 	<ul style="list-style-type: none"> Use 0.22 micron in-line filter Refrigerate unused vials Stable for 8-12 hours at RT Start up to 24 hrs prior to delivery/surgery IV loading dose over 15 minutes, followed by continuous infusion Isolated from goat milk—first drug from genetically engineered animals
Fibrinogen concentrate (human) (RiaSTAP)	Vial for reconstitution (900 to 1300 mg per vial)	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency	<ul style="list-style-type: none"> Thrombosis Hypersensitivity 	<ul style="list-style-type: none"> Each lot contains a different potency Refrigerate (do not freeze) Stable for 24 hrs after reconstitution if refrigerated Protect from light Administer IV through a dedicated line at a rate ≤ 5 mL/min
Abobotulinumtoxin A (Dysport)	Vial for reconstitution (300 units, 500 units)	Treatment of adults with cervical dystonia or for temporary improvement in the appearance of moderate to severe glabellar lines (facial lines)	<ul style="list-style-type: none"> Injection site pain Difficulty swallowing or breathing 	<ul style="list-style-type: none"> REMS program Black box warning: distant spread of toxin Use 21G needle to reconstitute Store in original container Expires 4 hours after reconstitution Refrigerate (do not freeze) Protect from light Administer using 30G needle Hologram on label/carton

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Golimumab (Simponi)	Prefilled syringe (50 mg/0.5 ml) Prefilled needle-less SmartJect autoinjector (50 mg/0.5 ml)	Treatment of moderately to severely active rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis in adults	<ul style="list-style-type: none"> • Infection 	<ul style="list-style-type: none"> • REMS program • Black box warning— infection risk • Refrigerate (do not freeze) • Protect from light • Do not shake • Bring to RT before injection • Patients may self-inject • Rotate injection sites
Japanese encephalitis vaccine (Ixiaro)	Single dose syringe (0.5 ml)	Active immunization for prevention of disease caused by Japanese encephalitis virus in adults	<ul style="list-style-type: none"> • Muscle aches/pains 	<ul style="list-style-type: none"> • Only for patients ≥ 17 years • Refrigerate (do not freeze) • Protect from light • White, opaque suspension • Shake before use • 2 IM injections given 28 days apart • Finish 1 week prior to exposure • Inject only into deltoid muscle • Contains sulfites
Canakinumab (Ilaris)	Vial for reconstitution (180 mg)	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults and children 4 years of age and older	<ul style="list-style-type: none"> • Infection 	<ul style="list-style-type: none"> • Black box warning— infection risk • Use 21G needle to reconstitute • Let stand for 5 minutes, invert 10 times, let stand for 15 minutes (do not shake) • Foaming may occur on reconstitution • Solution is clear or slightly yellow/brown • Use within 60 minutes or store in refrigerator for up to 4 hours • Inject every 8 weeks

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Reformulations				
Ibuprofen (Caldolor)	Vial for injection (400 mg/4 ml, 800 mg/8 ml) Previous formulations: Tablet, oral suspension, injection for neonates (Neoprofen)	Management of mild to moderate pain; management of moderate to severe pain as an adjunct to opioid analgesics; reduction of fever	<ul style="list-style-type: none"> Kidney damage Fluid retention Cardiovascular events GI bleeding 	<ul style="list-style-type: none"> Black box warning: CV events and GI bleeding Single use vial MUST be diluted prior to use Stable for 24 hours at RT Dose 200-800 mg IV over 30 minutes q 4-6 hr PRN Patient must be hydrated
Benzyl alcohol (Ulesfia)	5% topical lotion Previous formulation: Injection preservative	Topical treatment of head lice infestation in patients 6 months of age and older	<ul style="list-style-type: none"> Topical irritation 	<ul style="list-style-type: none"> Associated with toxicity in neonates—do not give if < 6 years Apply to dry hair/scalp Repeat application in 7 days Dose depends on hair length
Tadalafil (Adcirca)	Tablet (20 mg) Previous formulation: Tablet (as Cialis)	Treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability	<ul style="list-style-type: none"> Headache Eye/hearing effects 	<ul style="list-style-type: none"> Take 2 tablets daily Do not use with medications for erectile dysfunction Potential for many drug interactions
Bromocriptine (Cycloset)	Tablet (0.8 mg) Previous formulations: Capsule, tablet	Adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes	<ul style="list-style-type: none"> Hypotension Syncope 	<ul style="list-style-type: none"> Take within 2 hours of waking Take with food Do not use if breastfeeding
Zolpidem (Edluar)	Sublingual tablet (5 mg, 10 mg) Previous formulations: Tablet, extended release tablet, oral spray	Short term treatment of insomnia	<ul style="list-style-type: none"> Drowsiness Dizziness 	<ul style="list-style-type: none"> REMS program Class IV controlled substance
Oxybutynin (Gelnique)	Unit dose gel packet (100 mg) Previous formulations: Tablet, extended release tablet, syrup, patch	Treatment of overactive bladder	N/A	<ul style="list-style-type: none"> Apply once daily to abdomen, upper arms/shoulders, or thighs (rotate sites) Cover area with clothing to avoid transmission to others Wash hands after use

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Temozolomide (Temodar)	Vial for reconstitution (100 mg) Previous formulation: Capsule	Newly diagnosed glioblastoma multiforme; refractory anaplastic astrocytoma	<ul style="list-style-type: none"> • Hair loss • Nausea/vomiting 	<ul style="list-style-type: none"> • Store vials in refrigerator, bring to RT prior to reconstitution • Expires after 14 hours at RT • Only studied with PVC bags • IV infusion over 90 min is same as oral dose • Use a dedicated line • Flush before and after
Calcitriol (Vectical)	Topical ointment (3 mcg/gram) Previous formulations: Capsule, oral solution, injection	Topical treatment of mild to moderate plaque psoriasis	<ul style="list-style-type: none"> • Hypercalcemia 	<ul style="list-style-type: none"> • Apply topically twice weekly • Do not apply to eyes or face • Avoid excessive exposure to sunlight
Amlodipine/Valsartan/ Hydrochlorothiazide (Exforge HCT)	Tablet (5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg) Previous formulation: Amlodipine/valsartan (Exforge)	Treatment of hypertension	<ul style="list-style-type: none"> • Fluid retention • Kidney damage 	<ul style="list-style-type: none"> • Black box warning—avoid use in pregnancy • Take 1 tablet daily • Not indicated for initial therapy
Levonorgestrel (Plan B One-Step)	Tablet (1.5 mg) Previous formulation: Tablet (0.75 mg)	Prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure	<ul style="list-style-type: none"> • Heavier menstrual bleeding 	<ul style="list-style-type: none"> • CARE access program (REMS) • Take as soon as possible within 72 hours of intercourse • OTC for women ≥ 17 years old
Sumatriptan (Sumavel Dosepro)	Prefilled, single-dose, Needle-less subcutaneous delivery system (6 mg) Previous formulations: Tablet, nasal spray, subcutaneous injection	Treatment of migraine headache	<ul style="list-style-type: none"> • Bleeding, bruising, swelling, redness at injection site 	<ul style="list-style-type: none"> • Available in boxes of 6 doses • Inject SC in abdomen or thigh • Do not deliver dose through clothes • Makes loud noise when medication released • Use maximum of 2 doses in 24 hours • Separate doses by 1 hour

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Fentanyl (Onsolis)	<p>Buccal soluble film (200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg)</p> <p>Previous formulations: Patch, injection, lozenge, buccal tablet</p>	Management of breakthrough pain in adult patients with cancer	<ul style="list-style-type: none"> • Constipation • Decreased breathing 	<ul style="list-style-type: none"> • FOCUS limited access program (REMS) • Black box warning: patient should be non-opioid tolerant, potential for abuse • Class II controlled substance • Individually sealed, child-resistant foil packages • Apply to inside of cheek and hold in place for 5 minutes • Maximum of 4 doses/day • Do not convert from other doses of fentanyl
Ketorolac (Acuvail)	<p>Ophthalmic solution (0.45%) in single-use vials of 0.4 mL</p> <p>Previous formulations: Tablet, injection, ophthalmic solution (0.4% and 0.5%)</p>	Treatment of pain and inflammation following cataract surgery	<ul style="list-style-type: none"> • Increased intraocular pressure • Blurred vision • Delayed healing 	<ul style="list-style-type: none"> • Start the day prior to surgery and continue for 2 weeks after
Lamotrigine (Lamictal ODT)	<p>Orally disintegrating tablet (25 mg, 50 mg, 100 mg, 200 mg)</p> <p>Previous formulations: Tablet, chewable tablet</p>	Partial seizures, generalized seizures, or generalized tonic-clonic seizures; maintenance treatment of bipolar I disorder to delay the time to occurrence of mood symptoms	<ul style="list-style-type: none"> • Blurred vision • Somnolence 	<ul style="list-style-type: none"> • REMS program • Black box warning—serious skin rashes
Lamotrigine (Lamictal XR)	<p>Extended-release tablet (25 mg, 50 mg, 100 mg, 200 mg)</p> <p>Dose titration kits are available</p> <p>Previous formulations: Tablet, chewable tablet</p>	Adjunctive therapy for partial onset seizures with or without secondary generalization in patients ≥ 13 years of age	<ul style="list-style-type: none"> • Tremor • Balance problems 	<ul style="list-style-type: none"> • REMS program • Black box warning—serious skin rashes • Do not crush, chew, or divide tablets • Dose titration kit available
Diclofenac (Zipsor)	<p>Liquid filled capsule (25 mg)</p> <p>Previous formulations: Tablet, delayed release tablet, extended release tablet, patch, topical gel, ophthalmic solution</p>	Relief of mild to moderate acute pain	<ul style="list-style-type: none"> • Kidney damage • Fluid retention • Cardiovascular events • GI bleeding 	<ul style="list-style-type: none"> • Black box warning—cardiovascular and GI risk • Take 1 capsule 4 times daily • Do not convert from other doses of diclofenac

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Diclofenac (Cambia)	<p>Packet for reconstitution (50 mg)</p> <p>Previous formulations: Tablet, delayed release tablet, extended release tablet, patch, topical gel, ophthalmic solution</p>	Acute treatment of migraine in adults	<ul style="list-style-type: none"> • Kidney damage • Fluid retention • Cardiovascular events • GI bleeding 	<ul style="list-style-type: none"> • Black box warning—cardiovascular and GI risk • Mix packet with 1-2 ounces water prior to administration • Do not convert from other doses of diclofenac
Ciprofloxacin (Cetraxal)	<p>Preservative free otic solution (0.2%) in a single-use 0.25 mL container</p> <p>Previous formulations: Tablet, extended release tablet, oral suspension, injection, otic suspension, otic solution, ophthalmic solution, ophthalmic ointment</p>	Treatment of acute otitis externa	<ul style="list-style-type: none"> • Ear discomfort • Fungal superinfection 	<ul style="list-style-type: none"> • Instill into affected ear BID for 7 days • Only for use in the ear • Wash hands before use • Warm solution with hands prior to administration
Metformin/pioglitazone (Actoplusmet XR)	<p>Extended release tablet (1000/15 mg, 1000/30 mg)</p> <p>Previous formulation: Tablet</p>	Management of type 2 diabetes	<ul style="list-style-type: none"> • Lactic acidosis • Worsening of congestive heart failure • Diarrhea 	<ul style="list-style-type: none"> • REMS program • Black box warning—lactic acidosis and congestive heart failure • Pioglitazone is immediate release, metformin is extended release • Do not chew, cut, or crush tablets
Colchicine (Colcrys)	<p>Tablet (0.6 mg)</p> <p>Previous formulation: Tablet (non-FDA approved)</p>	Treatment of familial Mediterranean fever (FMF) in patients ≥ 4 years old	<ul style="list-style-type: none"> • Muscle damage • Bone marrow suppression • GI upset 	<ul style="list-style-type: none"> • Dose based on age • Potential for many drug interactions • Avoid grapefruit juice

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Treprostinil (Tyvaso)	Sterile solution for inhalation (0.6 mg/mL) in 2.9 mL ampoules Previous formulation: Injection	Treatment of pulmonary hypertension to increase walk distance	<ul style="list-style-type: none"> Hypotension Bleeding Cough Headache 	<ul style="list-style-type: none"> Administer undiluted using the Tyvasco Inhalation System Take 3 breaths QID (separate sessions by at least 4 hours), may increase to 9 breaths per session Do not mix with other medications Protect from light Store in original container
Me-too Drugs				
Besifloxacin (Besivance)	0.6% ophthalmic suspension	Treatment of bacterial conjunctivitis	<ul style="list-style-type: none"> Blurred vision Eye pain 	<ul style="list-style-type: none"> Use TID for 7 days Wash hands before use Do not touch dropper to eye
Iloperidone (Fanapt)	Tablet (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg)	Acute treatment of schizophrenia in adults	<ul style="list-style-type: none"> Hypotension 	<ul style="list-style-type: none"> Black box warning—increased mortality in elderly patients with dementia Must titrate dose Potential for many drug interactions
Dexlansoprazole (Kapidex)	Capsule (30 mg, 60 mg)	Healing and maintenance of all grades of erosive esophagitis; treatment of heartburn associated with GERD	<ul style="list-style-type: none"> Diarrhea Upper respiratory infection 	<ul style="list-style-type: none"> Swallow whole or open capsule and sprinkle on 1 tablespoon applesauce Potential for many drug interactions
Fenofibric acid (Trilipix)	Delayed release capsule (45 mg, 135 mg)	Decrease TG or increase HDL (with or without a statin)	<ul style="list-style-type: none"> Muscle damage 	<ul style="list-style-type: none"> REMS program
OTC Product				
Lansoprazole (Prevacid 24HR)	Capsule (15 mg) Previous formulation: Prescription product	Treatment of frequent heartburn (2 or more days per week)	<ul style="list-style-type: none"> Diarrhea 	<ul style="list-style-type: none"> Potential for many drug interactions

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Post-Test Questions

1. Which of the following correctly describes the FDA-approved indication for the following new drugs?
 - a. Febuxostat (Uloric), treatment of gout flare
 - b. Abobotulinumtoxin A (Dysport), management of lower back muscle tension
 - c. Prasugrel (Effient), reduction of thrombotic events in patients with acute coronary syndrome
 - d. Tolvaptan (Samsca), management of hypermagnesemia
2. Which of the following new medications increases risk of serious infections?
 - a. Ferumoxytol (Feraheme)
 - b. Golimumab (Simponi)
 - c. Milnacipran (Savella)
 - d. Ibuprofen (Caldolor)
3. Choose the incorrect/false answer from the choices below.
 - a. Japanese encephalitis vaccine (Ixiaro) is given intravenously.
 - b. Each lot of human fibrinogen concentrate (RiaSTAP) contains a different potency.
 - c. Golimumab (Simponi) is available as a prefilled syringe with needle and as a prefilled needle-less autoinjector.
 - d. Foaming may occur with reconstitution of canakinumab (Ilaris).
4. Which of the following medications require refrigeration?
 - a. Recombinant antithrombin (ATryn)
 - b. Human fibrinogen concentrate (RiaSTAP)
 - c. Canakinumab (Ilaris)
 - d. All of the above
5. Which of the following correctly describes the FDA-approved adult dosing for the following new drugs?
 - a. Everolimus (Afinitor), Take 1 tablet by mouth one time only
 - b. Prasugrel (Effient), Take 10 mg by mouth daily
 - c. Ferumoxytol (Feraheme), Give 125 mg IV at 8 sequential dialysis sessions
 - d. Artemether/lumefantrine (Coartem), Take 1 tablet by mouth TID for 7 days
6. Which of the following medications has a REMS program?
 - a. Human fibrinogen concentrate (RiaSTAP)
 - b. Everolimus (Afinitor)
 - c. Dronaderone (Multaq)
 - d. Japanese encephalitis vaccine (Ixiaro)