

New Drugs for 2009 (January – July 2009)

<b>Generic Name (Brand Name)</b>	<b>Dosage Form</b>	<b>Indication</b>	<b>Significant Adverse Effects</b>	<b>Notes</b>
<b>New Molecular Entities</b>				
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"> <li>Bleeding</li> </ul>	<ul style="list-style-type: none"> <li>REMS program</li> <li>Black box warning—risk of bleeding, do not use with history of stroke/TIA, CI if ≥75 years, discontinue 7 days prior to surgery</li> </ul>
Dronedrone (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"> <li>Arrhythmia</li> <li>GI upset</li> </ul>	<ul style="list-style-type: none"> <li>REMS program</li> <li>Black box warning—increased mortality in patients with severe heart failure</li> <li>Potential for many drug interactions</li> </ul>
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"> <li>Hypotension</li> <li>Dizziness</li> </ul>	<ul style="list-style-type: none"> <li>Give 2 doses separated by 3-8 days</li> <li>May interfere with MRI for up to 3 months</li> </ul>
Artemether/lumefantrine (Coartem)	Tablet (20 mg)	Treatment of acute, uncomplicated malaria	<ul style="list-style-type: none"> <li>Arrhythmia</li> </ul>	<ul style="list-style-type: none"> <li>Take with food for maximal absorption</li> </ul>
Everolimus (Afinitor)	Tablet (5 mg, 10 mg)	Treatment of advanced renal cell carcinoma	<ul style="list-style-type: none"> <li>Bone marrow suppression</li> <li>Risk of infection</li> <li>Mouth ulceration</li> </ul>	<ul style="list-style-type: none"> <li>Do not chew or crush</li> </ul>
Tolvaptan (Samsca)	Tablet (15 mg, 30 mg)	Treatment of clinically significant hypovolemic and euvolemic hyponatremia	<ul style="list-style-type: none"> <li>Thirst, dry mouth</li> <li>Frequent urination</li> </ul>	<ul style="list-style-type: none"> <li>Black box warning—initiate and re-initiate in a hospital</li> <li>Do not use if patient cannot sense and respond to thirst</li> <li>Use only in patients who make urine</li> <li>Potential for many drug interactions</li> </ul>
Milnacipran (Savella)	Tablet (12.5 mg, 25 mg, 50 mg, 100 mg)	Management of fibromyalgia	<ul style="list-style-type: none"> <li>GI upset</li> </ul>	<ul style="list-style-type: none"> <li>REMS program</li> <li>Black box warning—suicide</li> </ul>

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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"> <li>Increased liver enzymes</li> </ul>	<ul style="list-style-type: none"> <li>May cause gout flare</li> <li>May increase risk of stroke/heart attack</li> </ul>
<b>Biologics</b>				
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"> <li>Bleeding</li> <li>Infusion reactions</li> </ul>	<ul style="list-style-type: none"> <li>Use 0.22 micron in-line filter</li> <li>Refrigerate unused vials</li> <li>Stable for 8-12 hours at RT</li> <li>Start up to 24 hrs prior to delivery/surgery</li> <li>IV loading dose over 15 minutes, followed by continuous infusion</li> <li>Isolated from goat milk—first drug from genetically engineered animals</li> </ul>
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"> <li>Thrombosis</li> <li>Hypersensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Each lot contains a different potency</li> <li>Refrigerate (do not freeze)</li> <li>Stable for 24 hrs after reconstitution if refrigerated</li> <li>Protect from light</li> <li>Administer IV through a dedicated line at a rate ≤ 5 mL/min</li> </ul>
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"> <li>Injection site pain</li> <li>Difficulty swallowing or breathing</li> </ul>	<ul style="list-style-type: none"> <li>REMS program</li> <li>Black box warning: distant spread of toxin</li> <li>Use 21G needle to reconstitute</li> <li>Store in original container</li> <li>Expires 4 hours after reconstitution</li> <li>Refrigerate (do not freeze)</li> <li>Protect from light</li> <li>Administer using 30G needle</li> <li>Hologram on label/carton</li> </ul>

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

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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"> <li>• Kidney damage</li> <li>• Fluid retention</li> <li>• Cardiovascular events</li> <li>• GI bleeding</li> </ul>	<ul style="list-style-type: none"> <li>• Black box warning: CV events and GI bleeding</li> <li>• Single use vial</li> <li>• MUST be diluted prior to use</li> <li>• Stable for 24 hours at RT</li> <li>• Dose 200-800 mg IV over 30 minutes q 4-6 hr PRN</li> <li>• Patient must be hydrated</li> </ul>
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"> <li>• Topical irritation</li> </ul>	<ul style="list-style-type: none"> <li>• Associated with toxicity in neonates—do not give if &lt; 6 years</li> <li>• Apply to dry hair/scalp</li> <li>• Repeat application in 7 days</li> <li>• Dose depends on hair length</li> </ul>
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"> <li>• Headache</li> <li>• Eye/hearing effects</li> </ul>	<ul style="list-style-type: none"> <li>• Take 2 tablets daily</li> <li>• Do not use with medications for erectile dysfunction</li> <li>• Potential for many drug interactions</li> </ul>
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"> <li>• Hypotension</li> <li>• Syncope</li> </ul>	<ul style="list-style-type: none"> <li>• Take within 2 hours of waking</li> <li>• Take with food</li> <li>• Do not use if breastfeeding</li> </ul>
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"> <li>• Drowsiness</li> <li>• Dizziness</li> </ul>	<ul style="list-style-type: none"> <li>• REMS program</li> <li>• Class IV controlled substance</li> </ul>
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"> <li>• Apply once daily to abdomen, upper arms/shoulders, or thighs (rotate sites)</li> <li>• Cover area with clothing to avoid transmission to others</li> <li>• Wash hands after use</li> </ul>

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

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

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

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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"> <li>• Hypotension</li> <li>• Bleeding</li> <li>• Cough</li> <li>• Headache</li> </ul>	<ul style="list-style-type: none"> <li>• Administer undiluted using the Tyvasco Inhalation System</li> <li>• Take 3 breaths QID (separate sessions by at least 4 hours), may increase to 9 breaths per session</li> <li>• Do not mix with other medications</li> <li>• Protect from light</li> <li>• Store in original container</li> </ul>
<b>Me-too Drugs</b>				
Besifloxacin (Besivance)	0.6% ophthalmic suspension	Treatment of bacterial conjunctivitis	<ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Eye pain</li> </ul>	<ul style="list-style-type: none"> <li>• Use TID for 7 days</li> <li>• Wash hands before use</li> <li>• Do not touch dropper to eye</li> </ul>
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"> <li>• Hypotension</li> </ul>	<ul style="list-style-type: none"> <li>• Black box warning—increased mortality in elderly patients with dementia</li> <li>• Must titrate dose</li> <li>• Potential for many drug interactions</li> </ul>
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"> <li>• Diarrhea</li> <li>• Upper respiratory infection</li> </ul>	<ul style="list-style-type: none"> <li>• Swallow whole or open capsule and sprinkle on 1 tablespoon applesauce</li> <li>• Potential for many drug interactions</li> </ul>
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"> <li>• Muscle damage</li> </ul>	<ul style="list-style-type: none"> <li>• REMS program</li> </ul>
<b>OTC Product</b>				
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"> <li>• Diarrhea</li> </ul>	<ul style="list-style-type: none"> <li>• Potential for many drug interactions</li> </ul>

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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)