



MRx CLINICAL ALERT

YOUR MONTHLY SOURCE FOR DRUG INFORMATION HIGHLIGHTS

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■ KDIGO GUIDELINE UPDATE

An update was issued to the 2008 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for the prevention, diagnosis, evaluation, and treatment of hepatitis C virus (HCV) infection in chronic kidney disease (CKD). Due to a higher prevalence of HCV infection among CKD patients compared to the general population, HCV screening is now recommended at the time of initial evaluation of CKD, upon initiation of dialysis or transfer from another dialysis center, and at the time of kidney transplant evaluation. Additionally, the effectiveness and safety of oral direct-acting antiviral (DAA) therapy in CKD populations have largely impacted all aspects of HCV management. The updated guidelines recommend that all CKD patients infected with HCV be evaluated for treatment with a DAA. This includes candidates and recipients of kidney transplants and patients with HCV-associated glomerular disease. HCV treatment with interferon is no longer recommended due to poor tolerability, lower sustained virologic response (SVR) rates, and unfavorable outcomes in kidney transplant recipients.

The KDIGO guidelines recommend a DAA regimen be chosen based on patient factors, such as HCV genotype, degree of fibrosis, HCV treatment history, comorbidities, and transplant eligibility. Patients with glomerular filtration rate (GFR) ≥ 30 mL/min/1.73 m² may be treated with any licensed DAA-based regimen, while a ribavirin-free DAA-based regimen is recommended in advanced

CKD (GFR < 30 mL/min/1.73 m²). For kidney transplant recipients, assess potential drug interactions between the DAA regimen and concomitant transplant medications prior to HCV treatment.

The timing of DAA treatment in relation to kidney transplantation should be based on factors such as donor type (living or deceased), wait-list times, and liver fibrosis severity. Other key recommendations address HCV-associated kidney disease management, CKD testing in HCV-infected patients, transplantation of kidneys from HCV-infected donors, prevention of HCV transmission in hemodialysis units, and hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing.

■ BREAST CANCER RISK ASSESSMENT & REDUCTION

The United States (US) Preventive Services Task Force (USPSTF) updated their 2013 recommendations on both risk assessment for breast cancer and medication use to reduce risk of breast cancer. The USPSTF recommends that women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have a family history of *BRCA1/2* gene mutations should be assessed with a familial risk assessment tool. If a positive result is found with the risk assessment tool, women should receive genetic counseling and, if indicated, genetic testing. The USPSTF recommends against routine risk assessment, genetic counseling, or genetic testing for women who do not have a personal or family history of *BRCA1/2* gene mutations. The USPSTF

recommends that healthcare providers (HCPs) offer risk-reducing medications, including tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse effects. This recommendation is consistent with the previous 2013 recommendation, with the addition of aromatase inhibitors as an option for risk reduction.

■ ICER REPORTS ON DMD THERAPY

The Institute for Clinical and Economic Review (ICER) released their final report on therapies for Duchenne muscular dystrophy (DMD), a genetic condition characterized by progressive muscle weakening that is diagnosed predominantly in boys. DMD affects approximately 400 to 600 live male births each year in the US. ICER assessed the comparative clinical effectiveness and value of the corticosteroid deflazacort (Emflaza®, PTC) and Sarepta's exon-skipping therapies, eteplirsen (Exondys 51™) and golodirsen (investigational).

DMD affects multiple organ systems. Care is multifaceted and includes supportive care, such as physical and occupational therapy, to maintain ambulation. Corticosteroids (prednisolone, deflazacort) have been the mainstay of therapy. In September 2016, the first exon-skipping therapy, eteplirsen, was FDA-approved. Eteplirsen works by increasing the production of the deficient protein, dystrophin, to slow disease progression. Approval of another exon-skipping therapy, golodirsen, was denied in August 2019 when the FDA issued a complete response letter to Sarepta expressing concerns of infection and renal toxicity.

ICER determined that there is moderate certainty of comparable or better net health benefits with deflazacort compared to prednisone. Additionally, there is insufficient data to support the net health benefit of adding eteplirsen or golodirsen compared to using corticosteroids and supportive care alone. ICER determined that a discount of at least 73% from deflazacort's list price would be required to achieve commonly cited cost-effectiveness thresholds. A price could not be suggested for the exon-skipping therapies as there is no compelling evidence to support effectiveness for either drug. Notably, ICER also concluded that overall value should consider contextual benefits, such as deflazacort's ability to significantly reduce caregiver and family burden.

ICER recommends that patient groups and clinicians work with manufacturers to design clinical trials that measure patient-centered outcomes when developing effective drug therapies that are available at a fair market price. Additionally, payers should not require attestation of

benefits of deflazacort for continued coverage or any renewal criteria for the exon-skipping therapies, since continued clinical decline is expected with both treatments.



BEHAVIORAL HEALTH CORNER

AAP UPDATES ADHD GUIDELINES

In their 2019 clinical practice guidelines for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents, the American Academy of Pediatrics (AAP) provided minor updates in recommendations regarding diagnosis and management of ADHD in children from 4 years of age to their 18th birthday. The guidelines mirror diagnosis criteria set by the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, which was revised to the fifth edition (DSM-5). Appropriate diagnosis of ADHD includes ruling out ADHD-like symptoms stemming from alternative causes and identifying co-occurring conditions, such as depression, anxiety, substance use, autism, and sleep apnea.

Behavioral therapy is recommended as first-line treatment for preschool children (from 4 years of age to the 6th birthday) with ADHD. The AAP now defines behavioral therapy as parent training in behavior management (PTBM) and/or behavioral classroom interventions. These methods can be combined with FDA-approved medications for patients ages ≥ 6 years. The value of educational intervention and individualized instructional support is also described for students ages ≥ 12 years.

Primary care clinicians (PCCs), including pediatricians, are often called upon to diagnose and manage pediatric patients with ADHD. The AAP updated their process of care algorithm to assist clinicians in implementing the guidelines. When PCCs lack training, experience, or resources to diagnose and manage patients with ADHD, especially severe or complex cases, coordination of care for patients with ADHD with specialty clinicians is recommended. Additionally, a new publication by the Society for Developmental and Behavioral Pediatrics to address management of complex cases is anticipated in 2019. Notably, the AAP has identified systemic barriers to care of patients with ADHD and has created a companion article on addressing challenges regarding health insurance restrictions, appropriate payment for services, access to mental health specialists, and school collaboration.

DRUG INFORMATION (DI) HIGHLIGHTS

- As the FDA continues to monitor the presence of potentially carcinogenic nitrosamine impurities produced during manufacturing of the oral histamine-2 blocker ranitidine, voluntary recalls of all lots have been issued by 5 additional manufacturers. This includes Sanofi's over-the-counter (OTC) strength tablets, Novitium's prescription strength capsules, and OTC and prescription strengths by Dr. Reddy's and Perrigo. Lannett announced a voluntary consumer-level recall of all lots of ranitidine syrup 15 mg/mL, which requires a prescription. This is the first recall of a ranitidine oral liquid formulation due to nitrosamines.
- The American College of Obstetricians and Gynecologists (ACOG) published recommendations to expand OTC access to hormonal contraception without restrictions on age. ACOG states that continuation rates of hormonal contraception for OTC and prescription-only access are comparable. Venous thromboembolism (VTE) risk is minimal or non-existent with progestin-only products and is small for combination oral contraceptives compared to VTE risk during pregnancy or postpartum. Moreover, studies have shown that women can reliably self-screen to determine eligibility for hormonal contraceptive use. Additionally, pelvic and breast examinations, as well as cervical cancer and sexually transmitted infection screenings, should not be barriers to access. ACOG also supports pharmacist-provided contraception as an intermediate step to increase access, but OTC access of hormonal contraceptive should be the ultimate goal.
- While not available in the US at this time, the FDA granted a new indication to etanercept-szsz (Erelzi™), Sandoz's biosimilar to etanercept (Enbrel®), to treat psoriatic arthritis (PsA) and plaque psoriasis (PSO) in adults. Recommended maintenance doses are 50 mg subcutaneously (SC) once weekly.
- The American Heart Association (AHA) released a science advisory that summarizes the lipid and lipoprotein effects of prescription doses of the omega-3 fatty acids (FAs), eicosatetraenoic acid (EPA) and docosahexaenoic acid (DHA). For patients with very high triglycerides (TGs) (≥ 500 mg/dL), treatment with EPA+DHA at a dose of 4 grams/day reduces TGs by $\geq 30\%$ and increases low-density lipoprotein cholesterol (LDL-C); however, EPA-only agents did not raise LDL-C in this population. For hypertriglyceridemia (TG 200 to 499 mg/dL), EPA+DHA and EPA-only appear roughly comparable for TG lowering, resulting in a 20% to 30% reduction and no increase in LDL-C. The AHA concludes that prescription omega-3 FAs at doses of 4 grams/day are safe and effective for reducing TGs either as monotherapy or as an adjunct to a statin.
- The FDA recently approved a benralizumab (Fasenra®) 30 mg/mL prefilled single-dose auto-injector that allows patients to self-administer the dose. The treatment for severe asthma is also approved as a prefilled syringe for administration by an HCP.
- The FDA approved teriparatide (Bonsity) by Pfenex, a follow-on version of Eli Lilly's teriparatide (Forteo®). The parathyroid hormone analogue is indicated to treat the following patients at high risk for fracture: (1) postmenopausal women with osteoporosis; (2) men and women with osteoporosis associated with sustained systemic glucocorticoid therapy; and (3) men with primary or hypogonadal osteoporosis for the purpose of increasing bone mass. The recommended dose is 20 mcg SC once daily and can be self-administered using the approved 620 mcg/2.48 mL single-use pen. Therapy for more than 2 years per lifetime is not recommended. Product launch by Alvogen is pending therapeutic equivalence rating.

PIPELINE NEWS: UPCOMING PRESCRIPTION DRUG/BIOSIMILAR USER FEE ACT (PDUFA/BsUFA) DATES

- **Nov-Dec 2019:** dapagliflozin (Farxiga®); oral sodium glucose co-transporter 2 (SGLT2) inhibitor; type 2 diabetes mellitus (T2DM) cardiovascular (CV) outcomes; AstraZeneca.
- **Nov-Dec 2019:** RVT-802; postnatal thymus tissue transplant; pediatric congenital athymia; Enzyvant.
- **Nov 2019 - Jan 2020:** dulaglutide (Trulicity®); SC glucose-like peptide 1 (GLP-1) inhibitor; T2DM CV outcomes; Eli Lilly.
- **November 14, 2019:** cefiderocol; intravenous (IV) cephalosporin; complicated urinary tract infection; Shionogi.
- **November 15, 2019:** ethinyl estradiol/levonorgestrel; transdermal hormonal contraceptive; Agile.
- **November 21, 2019:** cenobamate; oral anticonvulsant; partial-onset seizure; SK Biopharmaceuticals.
- **November 29, 2019:** riluzole; oral transmucosal glutamine blocker; amyotrophic lateral sclerosis; Aquestive.
- **December 2, 2019:** atezolizumab (Tecentriq®); IV programmed death-ligand 1 (PD-L1) inhibitor; non-small cell lung cancer (NSCLC), 1st-line, with nab-paclitaxel; Genentech.
- **December 4, 2019:** luspatercept; SC transforming growth factor (TGF)-beta signaling modulator; beta-thalassemia; Acceleron.

RECENT FDA APPROVALS

DRUG NAME MANUFACTURER	DESCRIPTION
New Drugs	
dexamethasone (Hemady™) Dexcel	<ul style="list-style-type: none"> • 505(b)(2) NDA approval 10/03/2019; Orphan Drug • Indicated in combination with other anti-myeloma products for the treatment of adults with multiple myeloma • Corticosteroid • Tablet: 20 mg • Recommended dosage is 20 mg or 40 mg orally once daily, taken on specific days per the protocol regimen
cetirizine (Quzyttir™) Tersera	<ul style="list-style-type: none"> • 505(b)(2) NDA approval 10/04/2019 • Indicated for the treatment of acute urticaria in adults and children ages ≥ 6 months • Histamine-1 (H1) receptor antagonist • Injection: 10 mg/mL single-use vial • Recommended dosage is 2.5 mg, 5 mg, or 10 mg, depending on patient age; doses are administered IV once every 24 hours as needed in a medically supervised setting
trifarotene (Aklief®) Galderma	<ul style="list-style-type: none"> • NDA approval 10/04/2019 • Indicated for the topical treatment of acne vulgaris in patients ages ≥ 9 years • Retinoid • Cream: 0.005% • Apply a thin layer to the affected areas of the face and/or trunk once daily in the evening • Product availability is expected in November 2019
brolucizumab-bdll (Beovu®) Novartis	<ul style="list-style-type: none"> • BLA approval 10/07/2019; Priority Review • Indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD) • Human vascular endothelial growth factor (VEGF) inhibitor • Injection: 6 mg/0.05 mL solution in a single-dose vial (SDV) • Recommended dosage is 6 mg administered intravitreally once monthly for 3 doses, followed by 6 mg every 8 to 12 weeks
afamelanotide (Scenesse®) Clinuvel	<ul style="list-style-type: none"> • NDA approval 10/08/2019; Orphan Drug, Priority Review • Indicated to increase pain-free light exposure in adults with a history of phototoxic reactions from erythropoietic protoporphyria (EPP) • Melanocortin 1 receptor (MC1-R) agonist • Implant: 16 mg • Recommended dosage is a single implant (16 mg) inserted SC above the anterior supra-iliac crest every 2 months by a trained HCP using a suitable implantation device as determined by the manufacturer • Clinuvel will distribute directly to hospitals and clinics
asenapine (Secuado®) Noven	<ul style="list-style-type: none"> • 505(b)(2) NDA approval 10/11/2019 • Indicated for the treatment of adults with schizophrenia • Atypical antipsychotic • Transdermal system (patch): 3.8 mg/24 hours, 5.7 mg/24 hours, and 7.6 mg/24 hours • Recommended starting dose is one 3.8 mg/24 hours patch applied every 24 hours; may increase dose after 1 week; only 1 patch should be worn at any time; do not cut the patch or apply external heat sources

ANDA = Abbreviated New Drug Application; BLA = Biologics License Application; NDA = New Drug Application; Q = Quarter; sBLA = Supplemental Biologics License Application; sNDA = Supplemental New Drug Application; 505(b)(2) = FDA approval pathway that allows for submission of data from studies not conducted by or for the applicant.

RECENT FDA APPROVALS *continued*

DRUG NAME MANUFACTURER	DESCRIPTION
New Drugs <i>cont.</i>	
lasmiditan (Reyvow™) Eli Lilly	<ul style="list-style-type: none"> • NDA approval 10/11/2019 • Indicated for the acute treatment of migraine with or without aura in adults; not indicated for the preventive treatment of migraine • Serotonin (5-HT) 1F receptor agonist • Tablet: 50 mg and 100 mg • Recommended dosage is 50 mg, 100 mg, or 200 mg administered orally, as needed; no more than 1 dose should be taken in 24 hours; dose should not be administered < 8 hours before driving or operating machinery; safety of treating an average of > 4 migraine attacks in a 30-day period has not been established • Commercial availability is pending controlled substance scheduling; expected within 90 days of FDA approval
minocycline (Amzeeq™) Foamix	<ul style="list-style-type: none"> • 505(b)(2) NDA approval 10/18/2019 • Indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ages ≥ 9 years • Tetracycline • Foam: 30 g as a 4% concentration in a pressurized aerosol container • Apply topically to affected skin once daily at approximately the same time each day and at least 1 hour before bedtime, bathing, or swimming • Product availability is expected in January 2020
elexacaftor/ tezacaftor/ ivacaftor (Trikafta™) Vertex	<ul style="list-style-type: none"> • NDA approval 10/21/2019; Breakthrough Therapy, Orphan Drug, Priority Review • Indicated for the treatment of cystic fibrosis (CF) in patients ages ≥ 12 years who have at least one <i>F508del</i> mutation in the CF transmembrane conductance regulator (CFTR) gene • CF transmembrane conductance (CFTC) protein correctors (elexacaftor and tezacaftor) and a CFTR protein potentiator (ivacaftor) • Tablets: fixed-dose combination of elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg co-packaged with ivacaftor 150 mg • Recommended dosage is 2 fixed-dose tablets in the morning and 1 ivacaftor tablet in the evening taken approximately 12 hours apart; take with fat-containing food
Expanded Indications	
canagliflozin (Invokana®) Janssen	<ul style="list-style-type: none"> • sNDA approval 09/27/2019 • New indication to reduce the risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for heart failure (HF) in adults with T2DM and diabetic nephropathy with albuminuria • Recommended starting dose is 100 mg taken orally before the first meal of the day; may increase to 300 mg daily if tolerated
rituximab (Rituxan®) Genentech	<ul style="list-style-type: none"> • sNDA approval 09/27/2019; Orphan Drug, Priority Review • Expanded indication for the treatment of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) to include patients ages ≥ 2 years; previously only approved for GPA/MPA in adults • Recommended induction dosage for active GPA/MPA is 375 mg/m² via IV infusion once weekly for 4 weeks; give in combination with glucocorticoids

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RECENT FDA APPROVALS *continued*

DRUG NAME MANUFACTURER	DESCRIPTION
Expanded Indications <i>cont.</i>	
burosumab-twza (Crysvita®) Kyowa Kirin	<ul style="list-style-type: none"> • sBLA approval 09/30/2019; Orphan Drug • Expanded indication for the treatment of X-linked hypophosphatemia (XLH) to include pediatric patients 6 to 11 months of age; previously only approved in patients ≥ 1 year of age • Recommended starting dose for pediatric patients is 1 mg/kg for those weighing < 10 kg and 0.8 mg/kg for those weighing > 10 kg; minimum starting dose is 10 mg; dose should be administered every 2 weeks; may increase to a maximum of approximately 2 mg/kg (90 mg) per dose
sacubitril/valsartan (Entresto®) Novartis	<ul style="list-style-type: none"> • sNDA approval 10/01/2019 • New indication for the treatment of symptomatic HF with systemic left ventricular systolic dysfunction in pediatric patients ages ≥ 1 year • Recommended dosage in pediatric patients is weight-based and administered orally twice daily; dose is adjusted every 2 weeks as tolerated
emtricitabine/ tenofovir alafenamide (Descovy®) Gilead	<ul style="list-style-type: none"> • sNDA approval 10/03/2019; Priority Review • New indication for use in at-risk adults and adolescents weighing ≥ 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex; individuals must have a negative HIV-1 test immediately prior to initiating PrEP • Recommended dosage is 1 tablet (200/25 mg) orally once daily
rivaroxaban (Xarelto®) Janssen	<ul style="list-style-type: none"> • sNDA 10/11/2019 • New indication for the prophylaxis of VTE and VTE-related death during hospitalization and post hospital discharge in adults admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding • Recommended dosage for patients with creatinine clearance (CrCl) ≥ 30 mL/min is 10 mg once daily, in hospital and after hospital discharge, for a total duration of 31 to 39 days; avoid use in patients with CrCl < 30 mL/min
baloxavir marboxil (Xofluza®) Genentech	<ul style="list-style-type: none"> • sNDA approval 10/16/2019 • Expanded indication for the treatment of acute uncomplicated influenza in patients ages ≥ 12 years, who have been symptomatic for ≤ 48 hours to include patients at high risk of developing influenza-related complications • Recommended dosage is a single dose of 40 mg (two 20 mg tablets) for patients weighing 40 to < 80 kg and 80 mg (two 40 mg tablets) for patients weighing ≥ 80 kg
romiplostim (Nplate®) Amgen	<ul style="list-style-type: none"> • sBLA approval 10/17/2019; Orphan Drug • Expanded indication to include the treatment of thrombocytopenia in adults with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy • Recommended dosage is 1 mcg/kg SC once weekly; use the lowest dose to achieve and maintain a platelet count ≥ 50 × 10⁹/L

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Expanded Indications <i>cont.</i>	
dapagliflozin (Farxiga®) AstraZeneca dapagliflozin/ metformin (Xigduo® XR) AstraZeneca	<ul style="list-style-type: none"> • sNDA approval 10/18/2019 • New indication to reduce the risk of hospitalization for HF in adults with T2DM and established CV disease or multiple CV risk factors • Recommended dosage is dapagliflozin 10 mg orally once daily; for dapagliflozin/metformin, do not exceed dapagliflozin 10 mg/metformin extended-release 2,000 mg daily
onabotulinumtoxinA (Botox®) Allergan	<ul style="list-style-type: none"> • sBLA approval 10/18/2019 • New indication for the treatment of lower limb spasticity in pediatric patients ages 2 to 17 years, excluding spasticity caused by cerebral palsy • Total dose should not exceed the lower of 10 units/kg body weight or 340 units, in a 3-month interval when treating both lower limbs or the upper and lower limbs in combination
ustekinumab (Stelara®) Janssen	<ul style="list-style-type: none"> • sBLA approval 10/18/2019 • New indication for the treatment of adults with moderately to severely active ulcerative colitis • Recommended dosage is a single weight-based (defined in the product labeling) IV infusion administered by a HCP, followed by a 90 mg SC injection every 8 weeks that may be self-administered with proper training
aprepitant (Cinvanti®) Heron	<ul style="list-style-type: none"> • sNDA approval 10/21/2019 • Prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen in adults in combination with other antiemetic agents • The recommended dosage in adults is 130 mg on day 1 of chemotherapy cycle
niraparib (Zejula®) Tesaro	<ul style="list-style-type: none"> • sNDA approval 10/21/2019; Priority Review • New indication for the treatment of adults with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with ≥ 3 prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either (1) a deleterious or suspected deleterious <i>BRCA</i> mutation or (2) a genomic instability, and who have progressed ≥ 6 months after response to the last platinum-based chemotherapy; select patients based on FDA-approved companion diagnostic • Recommended dosage is 300 mg (3 capsules) orally once daily; continue until disease progression or unacceptable adverse reaction

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