Clinical Presentation – 1/22/21

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Acne Agents, Oral

- There is no recent information of significance in this class.

Acne Agents, Topical

- Amzeeq (minocycline) is a tetracycline approved to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. It is approved as a 4% foam to be applied to affected areas once daily and gently rubbed into the skin.
- Aralzo (tazarotene) is a retinoid approved for the topical treatment of acne vulgaris in patients 9 years of age and older. It is approved as a 0.045% lotion to be applied as a thin layer to the affected areas once daily. The eyes, mouth, paranasal creases, and mucus membranes should be avoided.

Analgesics, Narcotic Long

- Janssen has made a business decision to discontinue Duragesic. The product will remain available in generic formulations.
- The FDA has released a drug safety communication and a MedWatch for opioid pain relievers and opioid use disorder (OUD) agents recommending healthcare providers discuss and consider naloxone use with all patients at the time of prescribing. Furthermore, the FDA is requiring manufacturers for all opioid pain relievers and OUD treatments (e.g., buprenorphine, methadone and naltrexone) add recommendations on naloxone to the product labeling for healthcare providers to consider and discuss prescribing naloxone. When these meds are prescribed or renewed, the FDA is recommending the potential need for a naloxone prescription be evaluated. Corresponding updates will also be made to the Med Guides. In addition, for patients that are not receiving a prescription for an opioid analgesic or OUD treatment,

consideration should be given to prescribing naloxone for them if they are at a higher risk of opioid overdose (e.g., current/prior diagnosis of OUD or prior opioid overdose). The FDA also recommends healthcare providers consider prescribing naloxone when a patient has household members (e.g., children, close contacts) who may be at risk for accidental ingestion or opioid overdose.

Analgesics, Narcotic Short

- Dsuvia (sufentanil), a C-II controlled substance, is indicated for use in adult patients in a certified medically supervised healthcare setting for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Due to the risks of addiction, abuse and misuse with opioids, Dsuvia, as with all opioids should be reserved for patients for whom alternative treatment options have not been tolerated or have not provided adequate analgesia. Treatment with Dsuvia should be limited to administration by a HCP in a supervised setting for a maximum of 72 hours. It is approved as 30 mcg sublingual tablets housed in disposable single-dose applicators. The recommended dose is 30 mcg sublingually as needed with an hour between doses and a maximum daily dose of 12 tablets or 360 mcg. Dsuvia has a boxed warning regarding accidental exposure, life-threatening respiratory depression, addiction, abuse, and misuse, cytochrome P450 3A4 drug interaction, and risk of concomitant use with benzodiazepines and other CNS depressants. Contraindications include significant respiratory depression, acute or severe bronchial asthma, known or suspected gastrointestinal obstruction, and hypersensitivity to any components. Warnings are consistent with other opioid containing medications. Adverse reactions reported with Dsuvia were nausea, headache, vomiting, dizziness, and hypotension.
- Janssen has made a business decision to discontinue Ultram and Ultracet. The products will remain available in generic formulations.
- The American College of Physicians (ACP) and the American Academy of Family Physicians (AAFP) have published a new clinical practice guideline on managing acute pain associated from non–lower back, musculoskeletal injuries in adults who are outpatient. Recommendations are provided for nonpharmacologic and pharmacologic treatment modalities. Clinicians are recommended to treat patients with topical NSAIDs with or without menthol gel as first-line therapy to decrease or relieve symptoms and to improve physical functioning and the patient's treatment satisfaction. It is suggested that clinicians treat patients with oral NSAIDs (to reduce/relieve symptoms and to improve physical function) or with oral acetaminophen to reduce pain. Additionally, it is suggested that clinicians treat patients with specific acupressure for the reduction of pain and improvement of physical functioning or with transcutaneous electrical nerve stimulation to reduce pain. Lastly, the guidelines suggest against clinicians treating patients with opioids, including tramadol.

Angiotensin Modulator Combinations

- There is no recent information of significance in this class.

Angiotensin Modulators

- Mylan has made a business decision to discontinue eprosartan 600mg tablets. No other strengths or formulations of eprosartan will be available.

Antimigraine Agents, Other

- The DEA designated Reyvow (lasmiditan) as a Scheduled V controlled substance.

Antimigraine Agents, Triptans

- GSK has made a business decision to discontinue Imitrex 6mg SDV. Generics will remain available.

Antiparkinson's Agents

- Ongentys (opicapone) is a catechol-O-methyltransferase (COMT) inhibitor, indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. It is approved as 25 mg and 50 mg capsules. The recommended dose is 50 mg orally once daily at bedtime. Food should not be consumed for 1 hour before and at least 1 hour after taking opicapone. In patients with moderate hepatic impairment the recommended dose is 25 mg orally once daily at bedtime. Ongentys is contraindicated in patients with a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms and in patients concomitantly using non-selective monoamine oxidase inhibitors. Warnings include falling asleep during activities of daily living, hypotension and syncope, dyskinesia, hallucinations and psychosis, impulse control and compulsive disorders, and withdrawal-emergent hyperpyrexia and confusion. The most common adverse reactions were dyskinesia, constipation, increased blood creatine kinase, hypotension/syncope, and decreased weight.
- Kynmobi (apomorphine sublingual film) is a non-ergolamine dopamine agonist, indicated for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease. It was approved through a 505b2 NDA. It is approved as a sublingual film in 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg of apomorphine hydrochloride for sublingual administration. The recommended initial dose is 10 mg to be administered when a patient is in an "off" state and is supervised by an HCP where blood pressure and pulse can be monitored. If the 10 mg dose is tolerated and the response is sufficient, the initial dose should be 10 mg as needed up to 5 times per day to treat "off" episodes. However, if the dose is tolerated but the response is inadequate, the patient's usual PD medications should be restarted and up-titration of Kynmobi continued within 3 days. Dosage increases should occur in increments of 5 mg and under supervision of an HCP, until an effective and tolerable dose is reached. The usual dose range is 10 mg to 30 mg as needed for the acute, intermittent treatment of "off" episodes with doses separated by a minimum of 2 hours. If a single dose is not adequate for treating an "off" episode, a 2nd dose should not be given for the same "off" episode. The maximum dosage is 5 doses per day with a maximum of 30 mg/dose. The sublingual film should be administered whole and should not be cut, chewed, or swallowed. The film will disintegrate in ~ 3 minutes. An antiemetic (e.g., trimethobenzamide 300 mg three times a day) started 3 days before an initial dose should be given due to the high incidence of nausea and vomiting. The antiemetics should be continued if required to control nausea and vomiting

and usually no more than 2 months following the start of treatment. Concurrent use with 5HT3 antagonist antiemetics and alosetron is contraindicated due to profound hypotension and loss of consciousness when given concurrently. Kynmobi is also contraindicated in patients with hypersensitivity to apomorphine or any of its ingredients including sodium metabisulfite. Warnings include nausea and vomiting, falling asleep during activities of daily living, syncope and hypotension, oral mucosal irritation, falls, hallucinations and psychotic-like behavior, impulse control and impulsive behaviors, withdrawal emergent hyperpyrexia, and QTc prolongation. The most common reported adverse reactions were nausea, oral/pharyngeal soft tissue swelling and pain, paraesthesia, dizziness, and somnolence.

- Apokyn (apomorphine) is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. The starting dose is 0.2 mL (2 mg); give the first dose under medical supervision; titrate the dose to effect and tolerance; the maximum recommended dose is 0.6 mL. Available as 10 mg/mL single-patient-use cartridges for subcutaneous administration.

Bladder Relaxants

- Allergan has made a business decision to permanently discontinue all strengths of Enablex. Generic versions are available.

Glucagon Agents

- Diazoxide supenspenion is a generic for Proglycem suspension. It is a 50 mg/mL suspension and used for the management of hypoglycemia, it is dosed ast 3 mg/kg/day in divided doses evyer 8 to 12 hours.

H. pylori Agents

- Talicia is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of Helicobacter pylori infection in adults. The dosing is four capsules every 8 hours with food for 14 days.

Immunomodulators, Atopic Dermatitis

- Eucrisa (crisaborole) is now approved for the topical treatment of mild to moderate atopic dermatitis in patients ≥ 3 months of age. It was previously approved for use in patients ≥ 2 years old. Dosing remains the same for all ages, apply a thin layer to the affected area twice daily.
- Dupixent (dupilumab) is now approved for the treatment of patients ≥ 6 years of age with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids. Dupixent was previously approved for this indication in patients ≥ 12 years of age. The recommended dosing for pediatric patients 6 to 17 years of age is based on body weight with patients 15 to < 30 kg receiving an initial dose of 600 mg (two 300 mg injections) followed by 300 mg every 4 weeks. For patients 30 kg to < 60 kg, the initial dose is 400 mg (two 200 mg injections) followed by 200 mg every other week. For patients ≥ 60 kg, the initial dose is 600 mg (two 300 mg injections) followed by 300 mg every other week.

The pre-filled syringe dose for pediatric patients 6 to 11 years of age should be administered by a caregiver.

Intranasal Rhinitis

- There is no recent information of significance in this class.

Movement Disorders

- There is no recent information of significance in this class.

Neuropathic Pain

- Cymbalta (duloxetine) is now indicated for the treatment of fibromyalgia in pediatric patients ≥ 13 years of age. It was previously approved for the treatment of fibromyalgia in adults. Dosing for fibromyalgia is this expanded pediatric populations is 30 mg once daily. Cymbalta is also approved for use in major depressive disorder, diabetic peripheral neuropathic pain, chronic musculoskeletal pain in adults, and generalized anxiety disorder in adults and pediatric patients 7 years of age and older.
- Qutenza (capsaicin) is now approved to treat neuropathic pain associated with diabetic peripheral neuropathy of the feet. It was previously approved to treat neuropathic pain associated with postherpetic neuralgia. The recommended dose is a single 30-minute application on the feet of up to 4 patches. Treatment can be repeated every 3 months or as warranted by return of pain, but no more frequently than every 3 months. This product should not be dispensed to patients for self-administration or handling as only physicians or HCP under the supervision of a physician should administer and handle the product.

Oncology, Oral – Breast

- There is no recent information of significance in this class.

Oncology, Oral – Hematologic

- Xpovio (selinexor) is now approved for use in combination with bortezomib and dexamethasone for the treatment of adults with multiple myeloma who have received at least one prior therapy. The recommended dosing for this indication is 100 mg orally once weekly on day 1 of each week until disease progression or unacceptable toxicity in combination with bortezomib (1.3mg/m^2 subcutaneously once weekly on day 1 of each week for 4 weeks, followed by 1 week off). Xpovio was already approved for use in combination with dexamethasone for the treatment of multiple myeloma in certain patients with extensive treatment experience and for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in adults with systemic treatment experience.

Oncology, Oral – Lung

- Gavreto (pralsetinib) is now approved for the treatment of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy in adults and pediatric patients ≥ 12 years of age. It is also approved in patients ≥ 12 years of age with advanced or metastatic RET fusion-positive thyroid

cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). The recommended dosage for these indications is 400 mg orally once daily on an empty stomach. Gavreto is also indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer.

Oncology, Oral – Other

- There is no recent information of significance in this class.

Oncology, Oral – Prostate

- There is no recent information of significance in this class.

Oncology, Oral – RCC

- There is no recent information of significance in this class.

Oncology, Oral – Skin

- There is no recent information of significance in this class.

Phosphate Binders

- There is no recent information of significance in this class.

Platelet Aggregation Inhibitors

- Brilinta (ticagrelor) is now approved to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤ 5) or high-risk transient ischemic attack (TIA). The recommended dose for this indication is 180 mg as a loading dose followed by 90 mg twice daily for up to 30 days and given in combination with a loading dose of aspirin (300 to 325 mg) followed by 75 mg to 100 mg once daily.

Progestins for Cachexia

- There is no recent information of significance in this class.

Proton Pump Inhibitors

- The American Gastroenterological Association (AGA) and the Joint Task Force on Allergy-Immunology Practice Parameters (JTF) has issued a clinical practice guideline on the management of eosinophilic esophagitis (EoE). Recommendations include: for patients with symptomatic esophageal eosinophilia; proton pump inhibition is suggested over no treatment; topical glucocorticosteroids are recommended over no treatment; topical glucocorticosteroids are suggested rather than oral glucocorticosteroids. In patients in remission after a short-term course of topical glucocorticosteroids continuation of topical glucocorticosteroids are suggested over discontinuation of treatment. The use of anti-IgE therapy is suggested against for EoE. Additional recommendations pertain to use of an elemental diet, an empiric 6-food elimination diet, allergy testing-based elimination diet, as well as which therapies are only recommended in the context of a clinical trial.

Smoking Cessation

- The American Thoracic Society (ATS) published new practice guidelines on treatment of tobacco dependence in adults. The guidance maintains all patients who use tobacco should receive treatment for their dependence, and not simply be encouraged to stop. Strong recommendations include a preference of varenicline over a nicotine patch and bupropion in tobacco-dependent adults. Initiation of varenicline is also recommended prior to the individual being ready to stop tobacco use. Varenicline is also recommended over nicotine patch in patients with comorbid psychiatric conditions. ATS recommends initial controller therapy for at least 12 weeks (rather than standard 6-12 weeks).

Stimulants & Related Agents

- Wakix (pitolisant) is now approved to treat cataplexy in adults with narcolepsy whereas it was previously approved for the treatment of excessive daytime sleepiness associated with narcolepsy. The recommended dose for cataplexy and excessive daytime sleepiness in adults with narcolepsy is 17.8 mg to 35.6 mg daily upon wakening.

SINGLE PRODUCT REVIEWS

- Enbrel (etanercept) is now available in single dose vials (25 mg/0.5 ml)
- Enspryng (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. It is available as a 120mg/mL prefilled syringe. The dose is 120 mg subcutaneously every 2 weeks for 3 doses, then 120 mg every 4 weeks.
- AirDuo Digihaler (fluticasone propionate/salmeterol) is indicated for the treatment of asthma in patients ≥ 12 years of age who are not adequately controlled on a long-term asthma medication such as an inhaled corticosteroid or whose disease warrants initiation with a inhaled corticosteroid and long acting beta agonist. It is not indicated for the relief of acute bronchospasm. The AirDuo Digihaler is a dry powder inhaler with a built-in electronic module containing 60 actuations in 3 strengths (55/14 mcg per actuation, 113/14 mcg per actuation, and 232/14 mcg per actuation of fluticasone and salmeterol). The digital component measures inspiratory flow rates and sends this information to a companion mobile application using Bluetooth® wireless technology to track data over time and share with healthcare providers. The application can also be used to schedule reminders to take the AirDuo Digihaler as prescribed
- Breztri Aerosphere (budesonide/formoterol fumarate/glycopyrrolate), a combination of budesonide (an inhaled corticosteroid), glycopyrrolate (an anticholinergic), and formoterol fumarate (a LABA), is indicated for the maintenance treatment of patients with COPD. It is not indicated for the relief of acute bronchospasm or for the treatment of asthma. It is available as a pressurized MDI containing budesonide 160 mcg, glycopyrrolate 9 mcg, and formoterol fumarate 4.8 mcg per inhalation and is dosed as 2 oral inhalations twice daily. It was approved via a 505b2 NDA. Contraindications, warnings, and adverse reactions are consistent with products containing budesonide, formoterol fumarate, or glycopyrrolate.
- ArmonAir Digihaler contains fluticasone propionate, a corticosteroid, and is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older

- Hemady (dexamethasone) is approved for use in combination with other antimyeloma products to treat adults with multiple myeloma. It is approved as a 20mg tablet and may be given as 20mg or 40mg once daily on specific days dependent on the treatment protocol. Hemady was approved via the 505(b)(2) pathway and contraindications, warnings, drug interactions, and adverse reactions are similar to other systemic dexamethasone products.
- Semglee (insulin glargine) is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes and adults with type 2 diabetes. It was approved under the 505(b)(2) NDA pathway and is a biologic under a 351(a) BLA. It is supplied as 100 units/mL in a 10mL multiple-dose vial and 3mL single patient use prefilled pen. Dosing should be individualized based on the patient's metabolic needs, blood glucose monitoring, glycemic control, diabetes type, and previous insulin use. It is administered subcutaneously into the abdomen, thigh, buttocks, or upper arms once daily at the same time each day. The injection sites should be rotated to lower the risk of lipodystrophy and localized cutaneous amyloidosis. Blood glucose should be closely monitored if changing to Semglee and during the first weeks thereafter.
- Bafiertam (monomethyl fumarate) is approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. It was approved through a 505 (b)(2) NDA. It is available as 95 mg delayed-release capsules with a recommended maintenance dose of 190 mg orally twice daily following an initial dose of 95 mg twice daily for 7 days. Prior to initiating therapy with Bafiertam, a complete blood cell count including lymphocyte count and liver function testing is recommended. Contraindications, warnings, and adverse reactions are similar to dimethyl fumarate containing products.
- Kesimpta (ofatumumab) is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. It is available as a 20 mg/0.4 mL solution in a single dose prefilled syringe and Sensoready® pen. The recommended dose is 20 mg subcutaneously at weeks 0, 1, and 2 followed by 20 mg subcutaneously monthly starting at week 4. The subcutaneous injection may be administered into the abdomen, thigh, or outer upper arm and is intended for patient self-administration. The first injection should be given under supervision of a healthcare provider to evaluate for injection-related reactions. Kesimpta is contraindicated in patients with active HBV infection. Warnings include infections, injection related reactions, reductions in immunoglobulins, and risk of fetal harm. The most commonly reported adverse reactions were upper respiratory tract infection, headache, injection related reactions, and local injection site reactions. Ofatumumab is also marketed under the brand name Arzerra for the treatment of chronic lymphocytic leukemia (CLL).
- Diclotrex kit includes diclofenac sodium, camphor and menthol. Diclofenac sodium topical solution is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).