Virginia Medicaid Pharmacy & Therapeutics Committee Meeting

Debbie Moody, R.Ph., Pharmacist Account Executive
Nancy Eldin Pharm.D., Clinical Manager
Jeni Hodzic, Lead Formulary Analyst

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PDL Phase I – New Drug Review *(Therapeutic Class)*

Brand Drugs

- NAYZILAM™ *(Anticonvulsants)*
- KATERZIA™ *(Calcium Channel Blockers)*
- DUAKLIR® PRESSAIR® *(COPD)*

NAYZILAM™ (Anticonvulsants)

- **Nayzilam™ (midazolam) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity, such as seizure clusters or acute repetitive seizures, that are distinct from the usual seizure pattern experienced by patients 12 years of age and older with epilepsy.**

- **It is approved as a single-dose nasal spray unit delivering 5mg of midazolam in 0.1 mL of solution.**

- **Contraindications include hypersensitivity to midazolam and acute narrow-angle glaucoma.**

- **Warnings include CNS depression, particularly with concomitant CNS depressants or CYP3A4 inhibitors, suicidal behavior and ideation, and impaired cognitive function.**

- **Common adverse reactions include somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.**

- **Nayzilam is a DEA schedule IV medication. (May 2019)**

Recommend the drug be PDL Eligible

KATERZIA™ (Calcium Channel Blockers)

- **KATERZIA™ (amlodipine) oral suspension is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of:**
  - **Hypertension in adults and children 6 years and older, to lower blood pressure.**
  - **Coronary Artery Disease**
    - **Chronic Stable Angina**
    - **Vasospastic Angina (Prinzmetal's or Variant Angina)**
    - **Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.**
- **Adult recommended starting dose is 5 mg orally once daily**
- **Pediatric starting dose is 2.5 mg to 5 mg once daily.**
- **Approved as 1 mg/mL ready-to-use oral suspension.**

Recommend the drug be PDL Eligible

DUAKLIR® PRESSAIR® (COPD) *(Closed Class)*

- **Duaklir® Pressair® (aclidinium bromide and formoterol fumarate) is a combination of an anticholinergic and long acting beta agonist indicated for the maintenance treatment of COPD.**

- **It is approved as a 400 mcg of aclidinium bromide/12 mcg formoterol fumarate per actuation of the breath-actuated, multi-dose, dry powder inhaler.**

- **Warnings and contraindications are consistent with other anticholinergic/LABA combination products.**

- **Common adverse reactions include upper respiratory tract infection and headache. (March 2019)**

Recommend the drug be PDL Eligible

PDL Phase I – New Drug Review (Therapeutic Class)

Generic Drugs/New Strengths/New Dosage Forms

- ***(Bronchodilators, Beta Agonist)***
  - **ProAir® Digihaler™**

- ***(Glucocorticoids, Inhaled)***
  - **Dulera® 50 mcg/5 mcg**

Recommend the new dosage form and new strength be PDL Eligible

PDL Phase II – Annual Review Therapeutic Classes with Updates

Antimigraine Agents

Preferred Agents	Non-preferred Agents	
Relpax® (Brand is preferred over generic)	*almotriptan*	*Maxalt® tab & MLT*
sumatriptan succinate tab cartridge/nasal/vial/pen	*Alsuma®*	*Migranow™ Kit*
rizatriptan tab & MLT	*Amerge®*	*naratriptan*
	Axert®	*Onzetra™ Xsail™*
	Cambia®	*sumatriptan KITS*
	eletriptan (generic Relpax®)	*sumatriptan/naproxen (generic Treximet®)*
	Frova®	*Sumavel® Dosepro*
	frovatriptan (generic Frova®)	*Tosymra™*
	Imitrex®	*Treximet®*
	cartridge/nasal/pen/tab/vial	*Zembrace ™ SymTouch ™*
		Zomig® tab/nasal spray/ZMT

- **Tosymra™ (sumatriptan nasal spray) is indicated for the acute treatment of migraine with or without aura in adults.**
  - **It is approved as a single 10 mg spray to be administered in one nostril and may be repeated up to a maximum of 30 mg in 24 hours with at least one hour separating doses. (February 2019)**

Antimigraine Agents (Continued)

- **The American Academy of Neurology (AAN) and American Headache Society (AHS) issued new guidelines on pharmacologic treatment for pediatric migraine prevention as an update to the AAN's 2004 guidelines.**
  - **Key recommendations include:**
    - ***counsel patients and caregivers on lifestyle modifications (sleep habits, tobacco use);***
    - ***advise patients and caregivers that most trials of preventive medications have failed to show any benefit over placebo in children, except for propranolol which may "possibly" result in a 50% reduction in headache frequency;***
    - ***counsel patients/caregivers to treat an attack early for most benefit (first-line ibuprofen oral solution [10 mg/kg] in children and adolescents);***
    - ***sumatriptan/naproxen tablets and zolmitriptan nasal spray are options in adolescents;***
    - ***offer antiemetics to treat substantial nausea and vomiting;***
    - ***counsel patients/caregivers about medication overuse. (August 2019)***

Recommend that the class continue to be PDL Eligible

Antimigraine Agents, Others
Calcitonin Gene-Related Peptide (CGRP) and Others

Preferred Agents	Non-preferred Agents
Emgality™ Syringe **Emgality™ Pen**	*Aimovig™* *Ajovy™* *Reyvow™* *Ubrelvy™*

- **Emgality™ (galcanezumab-gnlm) is now indicated for the treatment of episodic cluster headache.**
  - **There is a new formulation of 100 mg/mL solution in a single-dose prefilled syringe.**
  - **It was previously approved for the treatment of migraine in a 120mg/mL prefilled pen and syringe for dosing in this indication. (June 2019)**

Antimigraine Agents, Others
Calcitonin Gene-Related Peptide CGRP and Others (Continued)

- Reyvow™ (lasmiditan), a serotonin (5-HT) 1F receptor agonist, is indicated for the acute treatment of migraines with or without aura in adults.
- It is not indicated for the preventative treatment of migraine.
- Warnings include operating machinery within 8 hours of a dose, CNS depression, serotonin syndrome, and medication overuse headache.
- Common adverse reactions include dizziness, fatigue, paresthesia, and sedation.
- Controlled substance Schedule V. (October 2019)

Antimigraine Agents, Others
Calcitonin Gene-Related Peptide CGRP and Others (Continued)

- **Ubrelvy™ (ubrogepant) a calcitonin gene-related peptide receptor (CGRP) antagonist, is indicated for the acute treatment of migraine with or without aura in adults.**
- **It is not approved for the preventive treatment of migraine.**
- **It is available in 50 mg and 100 mg tablets.**
- **Ubrelvy is contraindicated in patients concomitantly receiving CYP3A4 inhibitors.**
- **The most common adverse reactions were nausea and somnolence. (January 2020)**

Recommend that the class continue to be PDL Eligible

Opioid Dependency (Closed Class)
(includes oral buprenorphine & methadone)

Preferred Agents	Non-preferred Agents	
Opioid Dependency	**Closed Class**	
buprenorphine SL **Suboxone® film** **Sublocade™ SQ**	*Bunavail™* *buprenorphine/naloxone tab SL* *buprenorphine/naloxone film SL* *Cassipa®*	*Probuphine® Implant* *Zubsolv™*
naloxone syringe & vial **naltrexone tab** **Narcan® Nasal Spray** **Vivitrol®**	*Evzio®*	
Methadone Drugs		
	Dolophine® *Methadose® oral soln & tab* *methadone oral soln & tab*	

- **The generic for Narcan 4mg/spray nasal spray was approved by the FDA. (April 2019)**

Opioid Dependency (Closed Class)
***(includes oral buprenorphine & methadone)* (Continued)**

- **The US Department of Health and Human Services (HHS) published a new guideline for appropriate tapering or discontinuation of long-term opioid use.**
  - **Key recommendations include:**
    - ***(1) referral of patients with serious mental illness, high suicide risk, or suicidal ideation to a behavioral health provider prior to taper;***
    - ***(2) assessing patients for opioid use disorder if they show signs of opioid misuse and offer medication-assisted treatment if appropriate;***
    - ***(3) advising patients of risks for overdose if they abruptly return to their higher dose;***
    - ***(4) tapering by 5% to 20% every 4 weeks is common, but longer may be required;***
    - ***(5) and considering transition to buprenorphine for patients on high doses and unable to taper. (October 2019)***

Recommend that the class continue to be PDL Eligible

Opioids: Long Acting

Preferred Agents	Non-preferred Agents	
(Sch III-VI)		
Butrans® (buprenorphine) Transdermal Patch	*Belbuca (buprenorphine buccal film)* *buprenorphine (generic Butrans®)* *ConZip® (tramadol ER)*	*Ryzolt™ (tramadol ER)* *tramadol ER* *Ultram ER® (tramadol ER)*
(Sch II)		
fentanyl 12, 25, 50, 75 & 100 mcg patches morphine sulfate ER tab	*Arymo™ ER* *Duragesic®* *Embeda* *Exalgo®* *fentanyl 37.5 mcg, 62.5 mcg, and 87.5 mcg patches* *hydromorphone ER* *Hysingla ER™* *Kadian® ER* *Morphabond™ ER* *morphine ER cap (generic Avinza®)*	*morphine ER cap (generic Kadian®)* *MS Contin®* *Nucynta® ER* *Oramorph® SR®* *oxycodone-long acting* *OxyContin®* *oxymorphone ER* *Xartemis™ XR* *Xtampza ER®* *Zohydro ER™*

Opioids: Long Acting (Continued)

- **The FDA issued a Drug Safety Communication warning of serious harm to patients if opioid pain medications are discontinued or rapidly decreased in patients who were physically dependent on opioids.**

- **This warning comes in response to reports of withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.**

- **The package inserts for opioids will be updated to include additional guidance on safely decreasing doses. (April 2019)**

Opioids: Long Acting (Continued)

- **The CDC provided clarification on their 2016 Guideline for Prescribing Opioids for Chronic Pain.**

- **CDC stated that their guidelines on opioid prescribing were not intended to deny opioid therapy for pain management for any patients with chronic pain, particularly in patients with sickle cell disease, undergoing cancer treatment, or cancer survivors with chronic pain.**

- **The aim of the 2016 guideline was to ensure that clinicians and patients consider all safe and effective treatment options with the goal to reduce inappropriate use. (April 2019)**

Opioids: Long Acting (Continued)

- **The CDC issued a media statement advising against misapplication of their 2016 Guideline for Prescribing Opioids for Chronic Pain.**

- **Areas of misapplication include:**
  - **use in populations outside the scope of the guidelines;**
  - **instituting hard limits on dosages;**
  - **abruptly tapering or discontinuing opioid therapy;**
  - **and medication-assisted treatment for opioid use disorder.**

- **For patients already on long-term opioid therapy at high doses, the CDC advises:**
  - **to maximize non-opioid treatment,**
  - **empathetically review risks associated with continuing high-dose opioids,**
  - **collaborate with patient to taper dose,**
  - **taper dose slowly at an individualized pace,**
  - **and closely monitor to mitigate overdose risk. (May 2019)**

Recommend that the class continue to be PDL Eligible

Antifungals, Oral

Preferred Agents	Non-preferred Agents	
fluconazole tab/susp	*Ancobon®*	*ketoconazole*
griseofulvin susp	*clotrimazole (mucous mem)*	*Lamisil ® tab/granules*
nystatin tab/susp	*Cresemba®*	*Noxafil®*
terbinafine	*Diflucan® tab/susp*	*Onmel®*
	flucytosine	*posaconazole tab (generic for Noxafil®)*
	Gris-Peg®	*Sporanox® cap/soln*
	griseofulvin tab	Tolsura™
	griseofulvin ultramicrosize	*Vfend® tab/susp*
	itraconazole	*voriconazole tab & powder for susp*
	itraconazole solution (generic for Sporanox® soln)	

- **Posaconazole tablet, new generic for Noxafil® (November 2019)**

Recommend that the class continue to be PDL Eligible

Quinolones, (Second and Third Generations)

Preferred Agents	Non-preferred Agents	
Second Generation Quinolones		
ciprofloxacin susp/tab	*Cipro® IR & XR & susp* *ciprofloxacin ER*	*Noroxin®* *ofloxacin*
Third Generation Quinolones		
levofloxacin tab	Baxdela™ tab *Levaquin® tab/susp*	*levofloxacin susp* *moxifloxacin*

- **Baxdela™ (delafloxacin) is now approved for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria.**

- **Baxdela was previously approved for the treatment of ABSSSI (acute bacterial skin and skin structure infections). (October 2019)**

Recommend that the class continue to be PDL Eligible

Antivirals for Influenza, Oral

Preferred Agents	Non-preferred Agents
amantadine cap/tab/syrup **oseltamivir susp/cap**	*Flumadine® tab* *rimantadine* *Relenza Disk®* *Tamiflu® susp/cap* *Xofluza™*

- **Xofluza™ (baloxavir marboxil) is now approved for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza-related complications.**

- **The addition of high-risk patients was based on the CAPSTONE-2 clinical study. (October 2019)**

Recommend that the class continue to be PDL Eligible

Antihyperuricemics

Preferred Agents	Non-preferred Agents	
allopurinol	*colchicine tabs*	*Mitigare®*
colchicine caps	*Colcrys®*	*Uloric®*
Probenecid®	~~*Duzallo®*~~	~~*Zurampic®*~~
probenecid & colchicine	*febuxostat (generic Uloric®)*	*Zyloprim®*
	Gloperba®	

- **Ironwood has made a business decision to discontinue all strengths of Zurampic® (lesinurad) and Duzallo® (lesinurad/allopurinol). (April 2019)**

Recommend that the class continue to be PDL Eligible

Erythropoiesis Stimulating Proteins

Preferred Agents	Non-preferred Agents
Epogen® **Retacrit™**	*Aranesp®* *Mircera®* *Procrit®*

Erythropoiesis Stimulating Proteins (Continued)

- **The American Society of Clinical Oncology (ASCO) and American Society of Hematology (ASH) updated their 2010 recommendations for use of erythropoiesis-stimulating agents (ESAs) in patients with cancer.**
  - **They emphasize the intent of treatment be considered when weighing the benefits and risks of these agents (including thromboembolism).**
  - **Regarding biosimilars, they state clinicians should expect similar results among the various formulations (and biosimilars).**
  - **They note that ESAs can be used for incurable cancer for chemotherapy-associated anemia.**
  - **They can also be used for low-risk myelodysplastic syndrome.**
  - **The goal hemoglobin should be the lowest value that prevents need for transfusion; ESAs should be DC'd if there is a lack of hemoglobin increase by 1 to 2 g/dL by 6 to 8 weeks. (May 2019)**

Recommend that the class continue to be PDL Eligible

Anticoagulants (Closed Class)

Preferred Agents	Non-preferred Agents
Low Molecular Weight Heparin includes FactorXA Inhibitor	
enoxaparin	*Arixtra®* *fondaparinux* *Fragmin® syringe & vial* *Lovenox®*
Oral Anticoagulants	
Eliquis™ **Jantoven®** **Pradaxa®** **Xarelto®** **Xarelto® Starter Pack** **warfarin**	*Coumadin®* *Eliquis™ Dose Pack* *Savaysa™*

- **The American Heart Association/American College of Cardiology issued a focused update of the 2014 Guideline on the Management of Patients with Atrial Fibrillation.**
  - **The most notable recommendation change is that the novel oral anticoagulants (NOACs) are now recommended over warfarin to prevent stroke in patients with atrial fibrillation, except in those with moderate-to-severe mitral stenosis or a mechanical heart valve. (February 2019)**

Anticoagulants (Closed Class) (Continued)

FRAGMIN® (dalteparin sodium)

- **Now approved to reduce the recurrence of symptomatic venous thromboembolism (VTE) in pediatric patients 1 month of age and older.**
    - **The starting dose is based on age and weight of the patient for twice daily subcutaneous administration. (May 2019)**

XARELTO® (rivaroxaban)

- **Now approved for the prophylaxis of VTE and VTE-related death during hospitalization and post hospital discharge in adult patients 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 for bleeding.**
    - **The dose of Xarelto for this indication is 10 mg once daily during the hospital stay or following discharge for a total of 31 to 39 days. (October 2019)**

Recommend that the class continue to be PDL Eligible

Antihyperkinesis/CNS Stimulants (Closed Class)

Preferred Agents	Non-preferred Agents	
Amphetamine Drugs		
Adderall® XR **amphetamine salts combo** *(generic for Adderall IR)* **dextroamphetamine** *(generic for Dexedrine)* **Dyanavel™ XR susp** **Vyvanse® cap/chewable tab** (lisdexamfetamine)	*Adderall® IR (amphetamine salts combo)* *Adzenys XR ODT™* *Adzenys ER™ susp* *Adzenys® ER* *amphetamine salts combo XR* *amphetamine sulfate (generic Evekeo™)* *Desoxyn®*	*Dexedrine®* *dextroamphetamine SR & soln* *Evekeo™* *Evekeo™ ODT* *methamphetamine* *Mydayis ER™* *Procentra® soln* *Zenzedi™*
Methylphenidate Drugs		
All methylphenidate IR generic **Concerta®** **Daytrana® Transdermal** **Focalin® IR & XR** **QuilliChew ER™** **Quillivant™ XR susp**	*Adhansia™ XR* *Aptensio™ XR* *Cotempla XR-ODT™* *dexmethylphenidate IR & XR* *Jornay PM™* *Metadate CD®* *Metadate ER®*	*Methylin ER®, soln IR* *methylphenidate chew & soln* *methylphenidate ER tablet (generic for Concerta®)* *methylphenidate ER, LA, SR* *Ritalin® IR, LA® & SR®*

Antihyperkinesis/CNS Stimulants (Closed Class) (Continued)

Preferred Agents	Non-preferred Agents	
Miscellaneous Drugs		
atomoxetine *(generic for Strattera®)*	*armodafinil (generic Nuvigil™)*	*Sunosi™*
clonidine ER	*Intuniv®*	*Strattera®*
guanfacine ER	*modafinil*	*Wakix®*
	Nuvigil ™	
	Provigil®	

- **The American Academy of Pediatrics updated their guidelines for the management of ADHD.**
  - **Key recommendations include screening for co-occurring conditions such as depression, anxiety, and substance use, managing ADHD as a chronic condition, and using of evidence-based parent training in behavior management and/or behavioral classroom interventions as the first line of treatment for preschool-aged children.**
  - **A combination of approved medications combined with evidence-based behavioral management interventions is recommended for elementary and middle school-aged children. (October 2019)**

Antihyperkinesis/CNS Stimulants (Closed Class) (Continued)

WAKIX® (pitolisant)

- **A histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.**
- **Wakix is available in 4.45 mg and 17.8 mg tablets.**
- **It is intended to be dosed in the morning upon wakening with a weekly dose titration to 17.8 mg to 35.6 mg daily.**
- **There are dose adjustments recommended for patients with hepatic and renal impairment and patients who are poor metabolizers of CYP2D6 with a contraindication for patient with severe hepatic impairment.**
- **Warnings include prolongation of the QT interval.**
- **The most common adverse reactions reported in the clinical trials were insomnia, nausea, and anxiety. (August 2019)**

Recommend that the class continue to be PDL Eligible

Multiple Sclerosis Agents

Preferred Agents	Non-preferred Agents
Avonex®	*Ampyra®*
Avonex® Adm Pack	*Aubagio®*
Betaseron®	*Copaxone® 40 mg syringe®*
Copaxone 20 mg syringe®	*dalfampridine ER (generic for Ampyra®)*
Gilenya®	*Extavia® Kit*
Rebif® SQ	*Glatopa™*
Rebif® Rebidose Pen®	*Mavenclad®*
	Mayzent®
	Plegridy®
	Tecfidera™
	Vumerity™
	~~Zinbryta™~~

Multiple Sclerosis Agents **(Continued)**

- **The relapsing-remitting indication for:**
  - **Rebif® (interferon beta-1a),**
  - **Plegridy® (peginterferon beta-1a),**
  - **Tecfidera™ (dimethyl fumarate),**
  - **Avonex® (interferon beta-1a),**
  - **Ocrevus® (ocrelizumab),**
  - **Copaxone® (glatiramer),**
  - **Tysabri® (natalizumab),**
  - **Gilenya® (fingolimod),**
  - **Betaseron® (interferon beta-1b),**
  - **Extavia® (interferon beta-1b), and**
  - **Aubagio® (teriflunomide)**

  - **Has been updated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. (July-September 2019)**

Multiple Sclerosis Agents (Continued)

- **The American Academy of Neurology updated their 2002 guidelines regarding vaccine-preventable infections and immunizations for patients with multiple sclerosis.**
  - **In general, prescribers should recommend that patients with MS receive the influenza vaccine annually and follow local vaccine standards unless specific contraindications exist.**
  - **The local vaccine-preventable disease risks should be considered when counseling patients.**
  - **Additionally, patients with MS should receive counseling about infection risks associated with the specific immunosuppressive/immunomodulating (ISIM) medications as stated in the prescribing information (PI).**
  - **Screening and treatment of latent infections and immunization 4-6 weeks prior to starting ISIM medications is recommended.**
  - **In high risk populations, screening prior to ISIM therapy is recommended even if not specifically noted in the prescribing information.**
  - **Live –attenuated vaccines are not recommended in patients with MS receiving ISIM. (August 2019)**

Multiple Sclerosis Agents (Continued)

- **Vumerity™ (diroximel fumarate DR)**
  - **Approved for the treatment of relapsing forms of multiple sclerosis 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 231 mg delayed-release tablet.**
  - **The tablets should be swallowed whole and should not be administered with a high-fat, high-calorie meal or snack or with alcohol.**
  - **The contraindications, warnings, drug interactions, and adverse reactions are similar to dimethyl fumarate containing products. (November 2019)**

Recommend that the class continue to be PDL Eligible

Neuropathic Pain

Preferred Agents	Non-preferred Agents	
capsaicin OTC topical	*Cymbalta®*	*Lyrica® CR*
duloxetine 20, 30 & 60 mg	*Dermacinrx® PHN Pak™ Kit*	*Lyrica® soln*
gabapentin cap/tab/soln	*duloxetine 40 mg (generic for Irenka™)*	*Neurontin® cap/tab/soln*
lidocaine 5% patch	*Drizalma™ Sprinkle*	*pregabalin sol*
pregabalin cap	*Gralise™*	*Qutenza Kit® (Topical)*
	Horizant ™	*Savella™ & Savella™ Dose Pak*
	Irenka™	*Ztlido™ (lidocaine topical system)*
	Lidoderm® patch	
	Lyrica®	

Neuropathic Pain **(Continued)**

- **Lyrica® (pregabalin) is now approved as adjunctive therapy for partial onset seizures (POS) to include patients 1 month to under 4 years of age.**

- **Lyrica was previously approved in patients 4 years and older for this indication.**

- **It is also approved in adults for the treatment of neuropathic pain associated with spinal cord injury, fibromyalgia, diabetic peripheral neuropathy, and postherpetic neuralgia. (May 2019)**

- **Lyrica capsule and solution is now available as a generic, pregabalin. (July 2019)**

Neuropathic Pain (Continued)

DRIZALMA™ SPRINKLE (duloxetine DR)

- **Drizalma Sprinkle (duloxetine DR) has been approved for the treatment of major depressive disorder (MDD) in adults, generalized anxiety disorder in adults and pediatrics ≥ 7 years of age, diabetic peripheral neuropathic pain in adults, and chronic musculoskeletal pain in adults.**

- **It was approved through a 505(b)(2) NDA.**

- **It is available as a 20 mg, 40mg, and 60 mg DR capsule.**

- **The contraindications, warnings, drug interactions, and adverse reactions are similar to other duloxetine products. (July 2019)**

Neuropathic Pain (Continued)

- **The FDA issued a drug safety communication regarding serious breathing difficulties in patients using gabapentin (Neurontin®, Gralise™, Horizant™) or pregabalin (Lyrica®, Lyrica® CR) with respiratory risk factors.**

- **Notable risk factors include concomitant opioid pain medications or other CNS depressant drugs, patients with COPD, and elderly patients. (December 2019)**

Recommend that the class continue to be PDL Eligible

Non-Ergot Dopamine Receptor Agonists

Preferred Agents	Non-preferred Agents
pramipexole **ropinirole HCl**	*Mirapex® IR & ER* *Neupro®* *pramipexole ER* *Requip® XL* *ropinirole HCl ER*

- **GlaxoSmithKline has made a business decision to discontinue Requip® XL (ropinirole ER) in 4 mg, 6 mg, 8 mg, and 12 mg tablets. (July 2019)**

Recommend that the class continue to be PDL Eligible

Skeletal Muscle Relaxants

Preferred Agents	Non-preferred Agents	
baclofen	*Amrix®*	*orphenadrine citrate*
chlorzoxazone	*carisoprodol*	*orphenadrine/ASA/caffeine*
cyclobenzaprine HCL	*carisoprodol/ASA*	*Parafon Forte® DSC*
dantrolene sodium	*carisoprodol/ASA/codeine*	*~~Robaxin®~~*
methocarbamol	*cyclobenzaprine ER*	*Robaxin®-750 mg*
tizanidine tab	*Dantrium®*	*Skelaxin®*
	Fexmid®	*Soma®*
	Lorzone®	*tizanidine cap*
	metaxalone	*Zanaflex®*

- **Endo has made a business decision to discontinue Robaxin® 500 mg tablets. Supply is available through generic manufacturers (methocarbamol). (August 2019)**

Recommend that the class continue to be PDL Eligible

Smoking Cessation Agents

Preferred Agents	Non-preferred Agents
bupropion SR	*NicoDerm CQ® Patch*
Chantix®	*Nicorette® Gum/Lozenges*
Chantix® DS PK	*Nicotrol® Inhaler & NS*
nicotine gum/lozenge/patch	~~*Zyban®*~~

- **GlaxoSmithKline has made a business decision to discontinue Zyban® on or near July 2019. (July 2019)**

Recommend that the class continue to be PDL Eligible

Acne Agents Topical (includes benzoyl peroxide, clindamycin, erythromycin, minocycline, retinoids & combinations)

Preferred Agents	Non-preferred Agents	
COMBO BENZOYL PEROXIDE , CLINDAMYCIN, ERYTHROMYCIN, MINOCYCLINE TOPICAL		
benzoyl peroxide wash/cr/gel/ lot (OTC) **clindamycin/benzoyl peroxide (Duac®)** **clindamycin phosphate soln/swab** **erythromycin solution** **Panoxyl-4 Acne Cr Wash (OTC)** **Panoxyl 10 OTC**	*Acanya™ w/pump* *Acne Clearing System® (OTC)* *Aczone® Gel and Gel Pump* *Amzeeq™* *Avar Cleanser, Medicated Pad* *Avar-E* *Avar-E LS* *Avar LS Cleanser, Medicated Pad* *Azelex®* *Benzaclin®& Benzaclin® Pump* *BP 10-1* *Benzefoam™ regular & Ultra™* *Benzepro* *benzoyl peroxide wash/cr/gel/ lotion/foam/towelette (RX)* *benzoyl peroxide 6% , 9% cleanser (OTC)*	*BPO Kit* *Cleocin T®* *Clindacin™ Pac Kit* *Clindagel®* *clindamycin phosphate (generic for Clindagel®)* *clindamycin / benzoyl peroxide (generic for Acanya® Pump)* *clindamycin/benzoyl peroxide (generics for Benzaclin®)* *clindamycin phosphate foam, gel, lotion, med swab* *clindamycin/tretinoin (generic Veltin®)*

Acne Agents Topical (includes benzoyl peroxide, clindamycin, erythromycin, minocycline, retinoids & combinations) **(Continued)**

Preferred Agents	Non-preferred Agents	
	Delos™ Lotion™	*Sulfacetamide Cleanser ER*
	~~Duac® gel~~	*Sulfacetamide Cleanser, Shampoo, Susp*
	erythromycin gel/med. swab	*Sulfacetamide Sodium/Sulfur Cr, Susp, Sunscreen*
	Evoclin™	*SSS 10-5 Foam*
	Inova™	*Sulfacetamide/Sulfur/Cleanser, Cleanser Kit, Lotion Med. Pad*
	Lavoclen™ Cleanser & Kit	*Sulfacetamide / Sulfur / Urea Cleanser*
	Neuac™ topical/kit	*Sumadan Wash, Kit*
	Onexton™ gel & w/Pump	*Sumadan XLT*
	Ovace® Wash	*Sumaxin CP Kit*
	Ovace® Plus shampoo/cr/lotion/foam	*Veltin®*
	Pacnex® HP & LP	
	Panoxyl® 3% cr (OTC)	
	Promiseb® Complete	
	Rosula Cleanser	
	Se BPO® Wash Kit & cleanser	

Acne Agents Topical (includes benzoyl peroxide, clindamycin, erythromycin, minocycline, retinoids & combinations) (Continued)

Preferred Agents	Non-preferred Agents	
RETINOIDS/COMBINATIONS, TOPICAL		
Differin 0.1% gel (OTC) **Retin®A 0.025, 0.05, 0.1 % cr & 0.01, 0.025% gel**	*Acnefree® Severe Kit (OTC)* *adapalene 0.1% cr/gel/lot* *adapalene 0.3% gel/gel w/pump* *adapalene-benzoyl peroxide (generic Epiduo®)* *Aklief®* *Altreno™* *Atralin® 0.05% gel* *Avage® 0.1% cr* *Avita® 0.025% cr/gel* *Differin® 0.1% cr/gel/lot RX* *Differin® 0.3% gel pump* *Epiduo® & Epiduo® Forte Gel*	*Fabior™ 01% Foam* *Renova® 0.02% cr/cr pump* *Retin®-A Micro 0.04%, 0.1% gel* *Retin®-A Micro 0.08%, 0.04%, 0.1% pump* *Tazorac® cr/gel* *tazarotene 0.1% cr* *tretinoin 0.025, 0.1% cr & 0.01, 0.025, 0.05% gel* *tretinoin microsphere 0.04% & 0.1% gel* *Ziana® gel*

- **GlaxoSmithKline has made a business decision to discontinue Duac®. Supply is available through generic manufacturers. (July 2019)**

Acne Agents Topical (includes benzoyl peroxide, clindamycin, erythromycin, minocycline, retinoids & combinations) (Continued)

ACZONE® 7.5% (dapsone)

- Aczone 7.5% is now approved to treat acne vulgaris in patients ≥ 9 years of age.
  - It was previously approved to treat patients ≥ 12 years old. (September 2019)

AKLIEF® (trifarotene)

- Aklief is a retinoid approved for the treatment of acne vulgaris in patients ≥ 9 years of age.
  - It is available as a 0.005% cream for topical use once daily in the evening on clean dry skin. (October 2019)

AMZEEQ™ (minocycline)

- Amzeeq 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. (October 2019)

Recommend that the class continue to be PDL Eligible

Psoriasis Agents, Topical

Preferred Agents	Non-preferred Agents	
calcipotriene cr/oint/soln	*Calcitrene®*	*Micanol®*
	calcitriol	*Sorilux™*
	Dovonex®	*Taclonex® & Taclonex® Scalp*
	Duobrii™	*Vectical™*
	Enstilar® Foam	

- **Sorilux™ (calcipotriene) is now indicated for use in patients 4 years of age and older for the treatment of plaque psoriasis of the scalp and body.**
  - **It was previously approved for this indication in patients as young as 12 years of age. (November 2019)**

Psoriasis Agents, Topical **(Continued)**

- **American Academy of Dermatology and National Psoriasis Foundation published guidelines for management and treatment of psoriasis (PSO) in pediatric patients.**
  - **They recommend treatment of physical and psychosocial wellness and quality of life in peds with PSO.**
  - **Body surface area (BSA) plus Children's Dermatology Life Quality Index should be used to assess disease severity.**
  - **The guidelines recommend ongoing assessment for psoriatic arthritis (PsA), uveitis, obesity, CV risk factors, dyslipidemia, insulin resistance/diabetes, and mental health conditions.**
  - **The recommended topical treatments for PSO include:**
    - ***topical corticosteroids (off-label),***
    - ***tacrolimus 0.1% ointment (off-label) for PSO of face and genital region,***
    - ***calcipotriene/calcipotriol,***
    - ***calcipotriol/betamethasone dipropionate (ages ≥ 12 yo),***
    - ***tazarotene (off-label) + topical corticosteroids,***
    - ***topical anthralin,***
    - ***coal tar, and***
    - ***phototherapy/photochemotherapy.***
  - **Recommended systemic treatments include methotrexate, cyclosporine, systemic retinoids, and biologics, etanercept, infliximab, adalimumab, and ustekinumab. (January 2020)**

Recommend that the class continue to be PDL Eligible

Rosacea Agents

Preferred Agents	Non-preferred Agents
Metrocream®	*azelaic acid (generic for Finacea®)*
Metrogel®	*Finacea® foam/gel*
Metrolotion®	*ivermectin 1% cream (generic for Soolantra®)*
	metronidazole cr/gel/lot
	Mirvaso®
	Noritate®
	Rosadan™ Kit
	Soolantra®

- **Ivermectin 1% cream, new generic for Soolantra® (October 2019)**

Recommend that the class continue to be PDL Eligible

Androgenic Agents

Preferred Agents	Non-preferred Agents	
testosterone (generic for AndroGel®)	*Androderm®* *AndroGel®* *Axiron® soln* *Fortesta®* *Natesto Nasal Gel ®* *Testim®* *testosterone (generic for Axiron®)*	*testosterone gel/packet/pump (generic for Vogelxo™)* *testosterone (generic for Fortesta®)* *Vogelxo™ gel/packet/pump* *Xyosted™*

- **The American College of Physicians (ACP) released a new guideline for testosterone treatment in men with age-related low testosterone.**
  - **ACP recommends in this population, testosterone treatment only to help them improve their sexual function (preference of IM formulations over transdermal formulations, based on cost).**
  - **Symptoms should be reassessed within 12 months of starting therapy.**
  - **Treatment should be discontinued if symptoms fail to improve.**
  - **ACP recommends against initiating testosterone treatment in this population to improve energy, vitality, physical function, or cognition. (January 2020)**

Recommend that the class continue to be PDL Eligible

Bone Resorption Suppression and Related Agents
(includes bisphosphonates, calcitonins and others)

Preferred Agents	Non-preferred Agents	
Bisphosphonates		
alendronate tab	*Actonel®* *alendronate soln* *Atelvia DR®* *Boniva®* *Binosto™*	*etidronate* *Fosamax®tab & Fosamax® plus D* *ibandronate* *risedronate DR*
Calcitonins		
calcitonin-salmon nasal	*Miacalcin®*	
Others		
raloxifene	*Evista®* *Forteo®* *Tymlos™*	

Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonins and others) (Continued)

- **The Endocrine Society issued guidelines on the pharmacological management of osteoporosis in postmenopausal women.**
  - **In postmenopausal women at high risk for fractures, bisphosphonates are recommended to reduce fracture risk.**
  - **The fracture risk should be reassessed after 3 to 5 years of treatment at which time patients may either continue the bisphosphonate if determined to be a high risk or may have a "bisphosphonate holiday" if determined to be at low or moderate risk of fracture.**
  - **Postmenopausal women should be reassessed every 2 to 4 years.**
  - **Denosumab is considered an alternative initial treatment in postmenopausal women at high risk for fracture.**
  - **A drug holiday is not recommended in patients treated with denosumab and patients may be reassessed for continuation of denosumab or an alternate therapy after 5 to 10 years of treatment.**
  - **In patients with very high risk of fracture, teriparatide or abaloparatide is recommended for up to 2 years to reduce the risk of fracture. (March 2019)**

Recommend that the class continue to be PDL Eligible

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*)

Preferred Agents	Non-preferred Agents	
Diabetes Hypoglycemics: Injectable Amylin Analogs		
	SymLin® *SymLin® Pens*	
Diabetes Hypoglycemics: Injectable Incretin Mimetics (Closed Class)		
Byetta® (exenatide) **Bydureon™** (exenatide ER) **Victoza®** (liraglutide)	*Adlyxin™ (lixisenatide)* *Bydureon™ Bcise SQ (ER exenatide)* *Soliqua® 100/33 (insulin glargine & lixisenatide inj)* *Ozempic® (semaglutide)*	*Rybelsus® (semaglutide)* *Tanzeum™ (albiglutide)* *Trulicity™ (dulaglutide)* *Xultophy® 100/3.6 (insulin degludec & liraglutide inj)*
Oral Hypoglycemics DPP-IV Inhibitors & Combination (Closed Class)		
Janumet® **Janumet XR®** **Januvia®** **Jentadueto™** **Tradjenta™**	*alogliptin (generic Nesina™)* *alogliptin/metformin (generic Kazano™)* *alogliptin/pioglitazone (generic Oseni™)* *Jentadueto XR™*	*Kazano™* *Kombiglyze XR™* *Nesina™* *Onglyza™* *Oseni™*

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- **Xultophy® (insulin degludec/liraglutide) is now indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.**
  - **The indication was previously limited to use in patients who were inadequately controlled on basal insulin (< 50 units daily) or liraglutide (≤ 1.8 mg daily).**
  - **Dosing sections were updated to provide additional guidance for dosing in treatment-naïve patients and patients currently on basal insulin or GLP-1 receptor agonists. (March 2019)**

- **Soliqua® (insulin glargine/lixisenatide) is now approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.**
  - **The indication was previously limited to use in patients who were inadequately controlled on basal insulin (< 60 units daily) or lixisenatide. (March 2019)**

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*)
(Continued)

- The American College of Cardiology (ACC) and American Heart Association (AHA) released a new guideline on the primary prevention of cardiovascular disease (CVD).
  - According to ACC/AHA, the majority of CVD is related to smoking, poor diet, sedentary lifestyle, elevated body mass index and hypercholesterolemia, hypertension and diabetes (major risk factors).
  - ACC/AHA provide recommendations for the type of diet and amount of exercise for patients, particularly for patients with T2DM.
  - SGLT2 inhibitors and GLP-1 agonists are recommended in patients with T2DM with additional CV risk factors.
  - Prophylactic aspirin in middle-aged adults is now considered a Class IIb recommendation due to the lack of net benefit.
  - ACC/AHA recommends against the use of aspirin among patients > 70 years of age who are at risk for bleeding. (March 2019)

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- Ozempic® (subcutaneous semaglutide) is now available in a 3 mL cartridge with pen injector to allow a single pen to deliver 4 weekly doses of 1 mg for an individual patient.
    - The 1.5 mL formulation to deliver 1 mg doses required 2 separate pen devices to deliver 4 weekly doses for a month supply. (April 2019)

- Ozempic is now indicated to reduce the risk of major adverse cardiovascular events (MACE) in adults with T2DM and established cardiovascular disease.
    - The recommended dose is 0.25mg subcutaneously once weekly for 4 weeks followed by 0.5mg subcutaneously once weekly.
    - The recommended dose is also for the previously approved indication to improve glycemic control in adults with T2DM when used in conjunction with diet and exercise. (January 2020)

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- **American Diabetes Association published a consensus report on medical nutrition therapy (MNT), which now includes use in prediabetic patients.**
  - **Research shows that MNT can lower HbA1c at least as well as antidiabetic agents for T2DM.**
  - **Key recommendations include:**
    - ***patients with prediabetes who are overweight or obese should be referred to an intensive lifestyle intervention with personalized goals;***
    - ***adults with T1DM or T2DM should be referred for individualized MNT;***
    - ***macronutrient distribution should be based on individualized assessment of current eating patterns, preferences, and metabolic goals. (May 2019)***

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- Victoza® (liraglutide recombinant) is now approved as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with T2DM.
  - It was previously approved in adults for this indication as well as to reduce the risk of major CV events in adults with T2DM and established CVD.
  - The dosing for pediatric patients is 0.6mg SC once daily for the first week followed by weekly increases to 1.2 mg daily, then 1.8 mg daily if additional glycemic control is needed. (June 2019)
- The limitations for use of Bydureon™ BCise were revised following data from several DURATION trials including use with basal insulin.
  - The limitations for use note that Bydureon BCise is not recommended for concurrent use with prandial insulin as this has not been studied. (August 2019)

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- **The American Diabetes Association published updates to the 2019 Standards of Medical Care in Diabetes with the addition of Trulicity™ (dulaglutide) to the GLP1 receptor agonists that have demonstrated cardiovascular benefits in patients with T2DM based on the REWIND (Researching Cardiovascular Events with a Weekly Incretin in Diabetes) trial results.**
  - **The 2019 Standards of Medical Care updates include updates to the children and adolescents recommendations as a result of the FDA approval of Victoza® (liraglutide) in pediatric patients 10 years and older with T2DM. (August 2019)**

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- **Rybelsus® (semaglutide), an oral glucagon-like peptide-1 (GLP-1) receptor agonist, was approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.**
  - **Rybelsus is not recommended as first-line therapy for patients not controlled on diet and exercise, has not been studied in pateints with history of pancreatitis, and is not indicated to treat T1DM or diabetic ketoacidosis.**
  - **Rybelsus is approved in as 3mg, 7mg, and 14mg tablets to be dosed once daily 30 minutes prior to the first food, beverage, or other oral medication with no more than 4 oz of plain water.**
  - **If glycemic control is not achieved after 30 days, an additional increase to 14 mg daily is recommended.**
  - **Black box warning, contraindications, warnings, adverse effects, and drug interactions are similar to those for subcutaneous semaglutide (Ozempic®). (September 2019)**

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*) (Continued)

- **The American Diabetes Association (ADA) published the Standards of Medical Care in Diabetes - 2020.**
  - **Key revisions include two new sections: "Migrant and Seasonal Agricultural Workers," and "Pancreatic Diabetes or Diabetes in the Context of Disease of the Exocrine Pancreas."**
  - **A new recommendation was added regarding testing for prediabetes and/or T2DM in overweight/obese women who have ≥ 1 additional diabetes risk factor who are planning a pregnancy.**
  - **New recommendations were added around autoimmune conditions (thyroid disease, celiac disease) and comorbid conditions (hepatitis C infection).**
  - **Recently approved intranasal and SC glucagon formulations and the use of continuous glucose monitoring were added to the Hypoglycemia section.**
  - **Recently approved oral semaglutide was added as a treatment option.**
  - **The cardiovascular outcomes study discussion was revised and SGLT2 inhibitors and GLP-1 agonists are recommended for patients with ASCVD, heart failure, or CKD, independent of HbA1c.**
  - **Recommendations around blood pressure targets during pregnancy and the use of statins have been revised.**
  - **New recommendations for children and adolescents were added based on the approval of liraglutide in children ≥10 years old. (February 2020)**

Hypoglycemics: Amylin Analogs and Incretin Mimetics/Enhancers
(includes DPP-IV Inhibitors – *Closed Class*, GLP-1 Agonists & Comb – *Closed Class*)
(Continued)

- **Trulicity™ (dulaglutide) is now approved to reduce the risk of major adverse cardiovascular events (MACE; CV death, non-fatal MI, non-fatal stroke) in adults with T2DM who have established CV disease or multiple CV risk factors.**
  - **It was previously approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.**
  - **The initial dosage for MACE is 0.75 mg subcutaneously once weekly.**
  - **This dose may be increased to 1.5 mg once weekly if needed for glycemic control. (February 2020)**

Recommend that the class continue to be PDL Eligible

Hypoglycemics: Insulins

Preferred Agents	Non-preferred Agents
Insulin Mix	
Humalog® Mix 50/50 vial	*Humalog® Mix 50/50 Kwikpen*
Humalog® Mix 75/25 vial	*Humalog® Mix 75/25 Kwikpen*
Humulin® 70/30 vial	*Humulin® 70/30 pen (OTC)*
Novolog® Mix 70/30 pen/vial	*Novolin® 70/30 vial (OTC)*
Insulin N	
Humulin® N vial (OTC)	*Humulin® N pen*
	Novolin® N vial (OTC)
Insulin R	
Humulin® R vial	*Novolin® R vial (OTC)*
Long-Acting Insulins	
Lantus® Solostar® & vial (insulin glargine inj)	*Basaglar® KwikPen® (insulin glargine inj)*
	Toujeo® Solostar®(insulin glargine injection) 300 Units/mL
Levemir® pen/vial (insulin detemir)	*Tresiba® FlexTouch® Pen (insulin degludec) 100 U/ml, 200 U/ml*
Rapid-Acting Insulins	
Humulin 500 U/M pen & vial	*Admelog® Solostar Pen/vial*
Humalog® vial	*Apidra® cartridge/Solostar/vial*
Novolog® cartridge/Flexpen/vial	*Fiasp®*
	Humalog® Cartridge/Kwikpen®
	Humalog Jr. Kwikpen®
	Afrezza® cartridge (inhalation)

Hypoglycemics: Insulins (Continued)

- **The American Diabetes Association published updates to the 2019 Standards of Medical Care in Diabetes with new time-in-range goals for continuous glucose monitoring. (August 2019)**

- **Toujeo® Solostar and Toujeo® Max Solostar are now approved to improve glycemic control in pediatric patients ≥ 6 years old with diabetes mellitus. (December 2019)**

- **Fiasp® (insulin aspart) is now indicated to improve glycemic control in pediatric patients with diabetes mellitus including for use as a continuous subcutaneous insulin infusion.**
  - **It was previously approved for this indication in adults only. (January 2020)**

Recommend that the class continue to be PDL Eligible

Hypoglycemics: Metformins

Preferred Agents	Non-preferred Agents
Oral Hypoglycemics Biguanides	
metformin **metformin ER** *(generic for Glucophage® XR)*	*Fortamet®* *Glucophage® IR & XR* *Glumetza®* *Riomet® ER suspension* *Riomet® solution* *metformin ER (generic Fortamet®)* *metformin ER (generic Glumetza®)* *metformin solution (generic Riomet®)*
Oral Hypoglycemics Biguanide Combination Drugs	
glyburide/metformin	*glipizide/metformin* *Glucovance®*

Hypoglycemics: Metformins **(Continued)**

- **Bristol-Myers Squibb (BMS) has made a business decision to discontinue Glucophage® and Glucophage® XR.**
  - **Supply is available through generic manufacturers. (March 2019)**

- **Riomet® ER (metformin ER) is indicated to improve glycemic control in adults and pediatric patients ≥ 10 years of age with T2DM when used as an adjunct to diet and exercise.**
  - **It is approved as a 500 mg/5 mL powder for oral suspension packaged with the metformin-containing diluent for reconstitution.**
  - **Warnings, precautions, and adverse reactions are consistent with other metformin-containing products. (September 2019)**

Hypoglycemics: Metformins (Continued)

- **The Endocrine Society issued guidelines for the Treatment of Diabetes in Older Adults with particular focus on screening and treating patients aged 65 years and older with potential comorbities including renal impairment, cognitive dysfunction, and increased risks for poor medication adherence, hypoglycemia, falls, and loss of independence in daily living activities.**

  - **Outpatient diabetes regimens should minimize the risk of hypoglycemia and first line treatment should be metformin.**

  - **Oral agents with higher risks of hypoglycemia, such as sulfonylureas and meglitinides, should be avoided and insulin should be used sparingly. (April 2019)**

Recommend that the class continue to be PDL Eligible

Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class)

Preferred Agents	Non-preferred Agents
Farxiga™	*Invokamet®*
Glyxambi®	*Invokamet® XR*
Invokana®	*Qtern®*
Jardiance®	*Segluromet™ (ertugliflozin/metformin)*
Synjardy®	*Steglatro™*
	Steglujan™
	Synjardy® XR
	Xigduo™ XR

- **Qtern® (dapagliflozin, saxagliptin) is now approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.**
  - **The indication no longer contains the language limiting use to patients who have had inadequate control on dapagliflozin with or without saxagliptin. (May 2019)**

***Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class)* (Continued)**

- **American Diabetes Association (ADA) updated the Standards of Medical Care in Diabetes for 2019 with a focus on improving cardiovascular and renal health in people with diabetes.**

  - **Based on findings from DECLARE-TIMI 58 trial, (The Dapagliflozin Effect on Cardiovascular Events-Thrombosis in Myocardial Infarction 58), treatment with dapagliflozin (Farxiga™) showed a reduction in heart failure hospitalization and reduction in progression of chronic kidney disease.**

  - **The guidelines were updated to account for the prescribing information revision for dapagliflozin in patients with an estimated GFR ≥ 45 mL/min/1.73 m^2. (April 2019)**

Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class) (Continued)

- **Invokana® (canagliflozin) is now approved to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with T2DM and diabetic nephropathy with albuminuria.**
  - **The updated dosing recommendations for patients with eGFR 30 to < 45 mL/min/1.73m^2 and albuminuria > 300mg/day is for 100mg of Invokana orally once daily before the first meal of the day.**
  - **Invokana use was previously not recommended in patients with GFR < 45 mL/min/1.73m^2. (October 2019)**

- **Invokamet® (canagliflozin/metformin) and Invokamet® XR (canagliflozin/metformin) are now approved to reduce risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for heart failure in patients with T2DM and diabetic nephropathy with albuminuria > 300mg/day.**
  - **These drugs were previously approved to reduce the risk of MACE and as an adjunct to diet and exercise to improve glycemic control in patients with T2DM. (January 2020)**

***Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class)* (Continued)**

- **Farxiga™ (dapagliflozin) and Xigduo™ XR (dapagliflozin/metformin) are now approved to reduce the risk of hospitalization for heart failure in adults with T2DM and established CVD or multiple CV risk factors based on data from the DECLARE trial.**
    - **The dose of dapagliflozin for this indication is 10 mg once daily. (October 2019)**

Recommend that the class continue to be PDL Eligible

Cytokine and CAM Antagonists and Related Agents

(Closed Class)

Preferred Agents	Non-preferred Agents	
Enbrel®	*Actemra® SQ & ACTPEN*	*Orencia®*
Humira®	*Cimzia® & Cimzia® Syringe Kit*	*Rasuvo™*
methotrexate tab/ PFvial/ MDvial	*Cosentyx™*	*Remicade®*
	Dupixent®	*Rinvoq™*
	Entyvio®	*Skyrizi™*
	Ilaris®	*Siliq®*
	Ilumya™	*Simponi®*
	Kevzara® inj, pen	*Stelara® vial/syringe*
	Kineret®	*Taltz®*
	Olumiant®	*Tremfya™*
	Otezla®	*Trexall®*
	Otrexup®	*Xatmep™*
		Xeljanz™ & Xeljanz™ XR

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **The FDA issued a safety announcement regarding an increased risk of pulmonary embolism and death found in an ongoing clinical trial with the use of doses higher than the FDA approved dosing for rheumatoid arthritis for Xeljanz™ (tofacitinib) and Xeljanz™ XR.**
  - **Patients should be monitored for pulmonary embolism.**
  - **The clinical trial is expected to be completed by the end of 2019 with investigators switching patients to a lower dose. (March 2019)**

- **Based on interim data from an ongoing trial in patients with rheumatoid arthritis, FDA approved new boxed warnings for Xeljanz and Xeljanz XR for increased risk of blood clots and risk of death with 10 mg twice daily dose.**
  - **This is the recommended dose for ulcerative colitis (UC); although approved use for UC will be limited to select patients not treated effectively or who experience severe side effects with certain other medicines (e.g., TNF inhibitors). (July 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **Xeljanz™ XR (tofacitinib) is now approved for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers.**
  - **Use in combination with biological therapies for UC or with potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.**
  - **Xeljanz and Xeljanz XR are also approved for rheumatoid arthritis and psoriatic arthritis.**
  - **Xeljanz XR dosing for ulcerative colitis is 22mg once daily for at least 8 weeks for the induction period followed by 11mg once daily for the maintenance dose. (December 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **Cimzia® (certolizumab pegol) is now approved for the treatment of non-radiographic axial spondyloarthritis (nr-asXpA) in adults with objective signs of inflammation.**
  - **The dose for this indication is 400 mg (2 x 200 mg) subcutaneously initially and at weeks 2 and 4, followed by 200 mg every 2 weeks or 400 mg every 4 weeks.**
  - **Cimzia was already approved for the treatment of ankylosing spondylitis, rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, and Crohn's disease. (March 2019)**

- **Otezla® (apremilast) is now approved to treat adults with oral ulcers associated with Behçet's disease.**
  - **The dosage for this indication is consistent with psoriasis (PSO) and psoriatic arthritis (PSA) indications such that after a 6 day ramp up period, the maintenance dose is 30 mg twice daily. (July 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **Rinvoq™ (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.**
  - **Use in combination with other JAK inhibitors, biologic DMARDs , or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.**
  - **Rinvoq should not be initiated in patients with an absolute neutrophil count (ANC) less than 1000/mm^3, absolute lymphocyte count less than 500 cells/ mm^3, or hemoglobin less than 8g/dL.**
  - **There are boxed warnings for serious bacterial, viral, and fungal infections that may lead to hospitalization or death, latent and active tuberculosis, lymphoma and other malignancies, and thrombosis.**
  - **Additional warnings include gastrointestinal perforation, embryo-fetal toxicity, use with live vaccines, and laboratory monitoring for changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids.**
  - **Common adverse reactions include upper respiratory tract infections, nausea, cough, and pyrexia. (August 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **The American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network published a 2019 update on the treatment of ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (SpA).**
  - **In general, recommendations for AS and nonradiographic axial (SpA) are similar and include a level of evidence for the recommendation.**
  - **TNF antagonists (but not a specific one) are recommended as the first biologic.**
  - **Secukinumab (Cosentyx™) or ixekizumab (Taltz®) are then recommended over a second TNF antagonist if first does not produce a response.**
  - **All the prior mentioned agents are recommended over tofacitinib (Xeljanz™).**
  - **A concurrent low-dose methotrexate with a TNF antagonist is not recommended.**
  - **The guidelines also recommend against a strict treat-to-target strategy and recommend against discontinuing or taper of biologics in stable disease.**
  - **Sulfasalazine provides an option for select patients who cannot take a TNF antagonist. (August 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **Taltz® (ixekizumab) is now approved for the treatment of adults with ankylosing spondylitis.**
  - **The dose for this indication is 160 mg SC initially followed by 80 mg SC every 4 weeks.**
  - **Approval for this indication was based on the results from the COAST-V and COAST-W trials.**
  - **Taltz was previously approved for the treatment of plaque psoriasis and psoriatic arthritis. (August 2019)**

- **Olumiant® (baricitinib) is now available in a 1 mg tablet for use in recommended dose adjustments for patients with moderate renal impairment or taking organic anion transporter (OAT3) inhibitors. (October 2019)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **Stelara® (ustekinumab) is now approved for the treatment of moderately to severely active ulcerative colitis in adults.**
  - **The dose for this indication is based on weight when given initially as IV (range of 260 mg to 520 mg) and 90 mg subcutaneously every 8 weeks following the initial dose and starting at week 8.**
  - **Stelara was already approved for use in plaque psoriasis, psoriatic arthritis, and crohn's disease. (October 2019)**

- **Cosentyx™ (secukinumab) is now approved for dosing as 300 mg every 4 weeks in patients who are symptomatic on the previously approved maintenance dose of 150 mg every 4 weeks for treatment of ankylosing spondylitis in adults. (January 2020)**

Cytokine and CAM Antagonists and Related Agents (Closed Class) (Continued)

- **The Institute for Clinical and Economic Review (ICER) released its final report on Janus kinase (JAK) inhibitors to treat RA.**
  - **In patients with moderately-to-severely active RA and inadequate response to cDMARDs, upadacitinib (Rinvoq®) and tofacitinib (Xeljanz™) provide substantial net health benefits compared to cDMARDs and a comparable or better net health benefit compared to adalimumab (Humira®).**
  - **Upadacitinib (Rinvoq®) achieved common thresholds for cost-effectiveness compared to adalimumab (Humira®).**
  - **Baricitinib (Olumiant®) was not evaluated since indication does not include targeted immune modulators (TIMs) naive patients. (January 2020)**

Recommend that the class continue to be PDL Eligible

Therapeutic Classes without Updates
(Reviewed by the Department)

Analgesics

- **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)** ***(includes Cox-2 inhibitors and topical agents)***
- **Opioids: Short Acting** ***(includes combination drugs and lozenges)***

Antibiotics / Anti-Infectives

- **Antibiotics** ***(topical)***
- **Cephalosporins** ***(Second and Third Generations)***
- **Gastrointestinal, Antibiotics**
- **Ketolides & Macrolides** ***(Adult and Pediatric)***
- **Quinolones** ***(Otic)***

Antivirals

- **Antivirals for Herpes (HSV)**

Therapeutic Classes without Updates (Reviewed by the Department)

Cardiac

- **Platelet Aggregation Inhibitors**

Contraceptives

- **Long-Acting Reversible Contraceptives *(includes IUDs & injectables)***

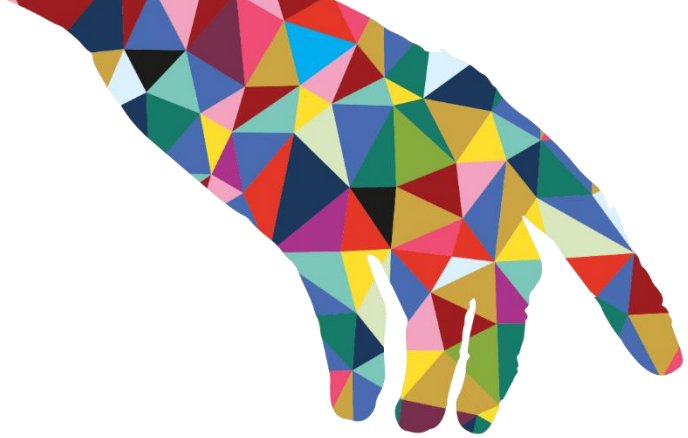
Dermatologic Agents (Topical)

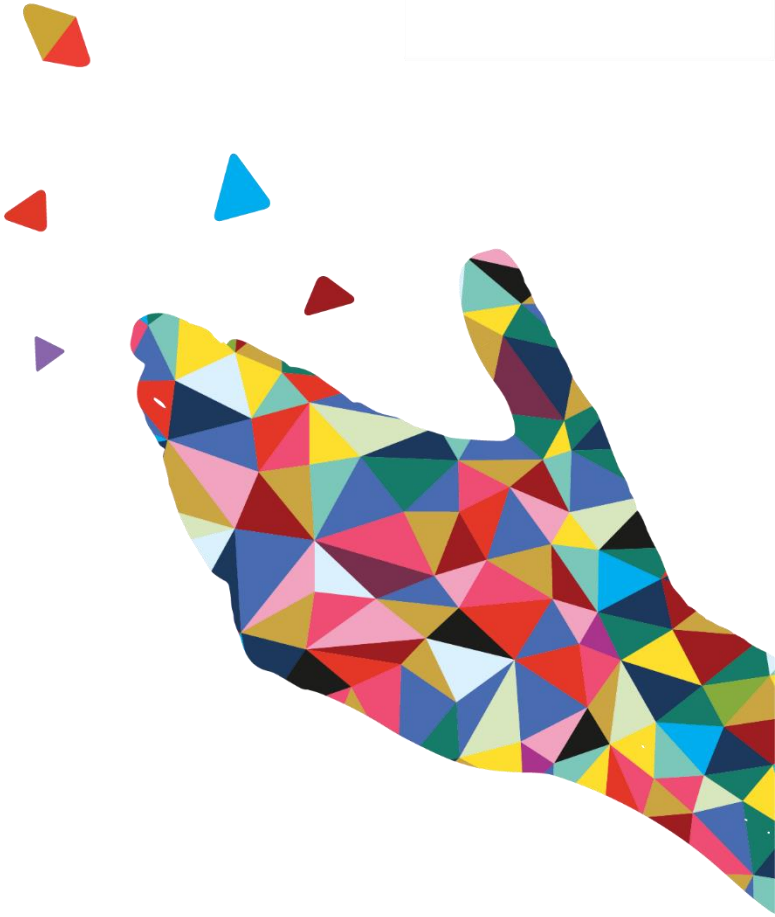
- **Antifungal Agents**
- **Antivirals, Topical**

Endocrine and Metabolic Agents

- **Estrogens *(vaginal and oral)***
- **Hypoglycemics: Alpha-Glucosidase Inhibitors**
- **Hypoglycemics: Meglitinides**
- **Hypoglycemics: Sulfonylureas**
- **Hypoglycemics: Thiazolidinediones**
- **Pancreatic Enzymes**
- **Progestational Agent**

Recommend ALL classes remain PDL Eligible





THANKS

BREAK FOR FINANCIAL MEETING