Virginia's Department of Medical Assistance Services
Pharmacy and Therapeutics Committee Meeting

Tuesday September 14, 2021 - 10:00 a.m.

Please click on this link to join the WebEx
Audio Access: 866-692-4530; Pin 967 0500

This is an electronic public meeting held in accordance with section 17.a of chapter 1 of the 2021 Special Session II at https://lis.virginia.gov/cgi-bin/legp604.exe?213+ful+CHAP0001+pdf
The FOIA Councils "Electronic Meetings Public Comment" form for submitting feedback on this electronic meeting may be accessed at http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm

Welcome and Comments from DMAS' Chair — **Chethan Bachireddy, MD, CMO, Chair**

Call to Order — **Chethan Bachireddy, MD, CMO, Chair**

Drug Utilization Review (DUR) Board Update — **Rachel Cain, PharmD**

Old business:

- Respiratory Drugs (excludes ICS and SABAs) Members less than 4 years of age.
- Utilization of Anticoagulants Reversal When using the Novel Anticoagulants.
- Type 2 diabetes and treatment with oral hypoglycemics.

PDL Management — **P&T Committee Members**

PDL Phase II – New Drug Review (Therapeutic Class)

Brand Drugs

- Kloxxado® Spray (Nasal) (*Opiate Dependence Treatments*)
- Plegridy® (IM) & Ponvory™ (Oral) (*Multiple Sclerosis Agents)*
- Qelbree® (Oral) (*Stimulants and Related Agents*)

Generics Drugs and New Dosage Forms –

- Tazarotene generic for Fabior® (*Acne Agents, Topical)*
- Skyrizi™ Pen new dosage form (*Cytokine and Cam Antagonists)*
- Clobetex® Kit new dosage form (*Steroids, Topical Very High)*

PDL Phase I – Annual Review -Therapeutic Classes with Updates

Antibiotics/Anti-Infectives

- Antibiotics, Vaginal

Antivirals

- HIV *(Potential new PDL class and new Closed Class)*

Blood Modifiers

- Bile Salts

Cardiac Medications

- Angiotensin Modulators II *(includes Direct Renin Inhibitors & combination products)*
- Lipotropics, Statins
- Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor agents, Fibric Acid derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin derivatives, Oligonucleotide Inhibitors and Omega 3 agents)
- Pulmonary Arterial Hypertension Agents, Oral/Inhaled/Injectable (includes Endothelin-1 agents, PDE-5 Inhibitors, Prostacyclin analogues, Prostacyclin Vasodilator, Soluble Guanylate Cyclase Stimulators) Central

Central Nervous System

- Anticonvulsants *(Potential new Closed class)*
- Movement Disorder Agents *(Potential new PDL class and new Closed Class)*

Dermatitis

- Immunomodulators, Atopic Dermatitis *(Potential new PDL class and new Closed Class)*

Endocrine & Metabolic Agents

- Hereditary Angioedema (HAE)

Genitourinary

- Bladder Relaxants

Ophthalmic

- Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers)
- Antibiotics
- Anti-inflammatory/ immunomodulators *(Potential new PDL class and new Closed Class)*

Respiratory

- Bronchodilators, Long-Acting Beta Adrenergics
- Glucocorticoids *(includes nebulized solutions, metered dose inhalers and combinations)* *(Closed Class)*
- Intranasal Rhinitis (includes Antihistamines and Corticosteroids)

Next Meeting – Voting Meeting TBD **Chair**

Spring Meeting - March 17, 2022 (tentative) **Chair**

VIRGINIA FREEDOM OF INFORMATION ADVISORY COUNCIL

COMMONWEALTH OF VIRGINIA ELECTRONIC MEETINGS PUBLIC COMMENT FORM

WE NEED YOUR HELP--Please give us your feedback regarding how meetings using electronic communications technology compare to traditional meetings where everyone is present in the same room at the same time.

1. Name of the public body holding the meeting: _VA Dept of Medical Assistance Services Pharmacy & Therapeutics Committee Meeting

2. Date of the meeting: Thursday, September 14, 2021,

3. What are your overall thoughts or comments about this meeting?
   _____

4. Where did you attend this meeting -- main meeting location OR from a remote location? (Circle one)

5. Technology used for the meeting (audio only or audio/visual, devices and/or software used--please be as specific as possible--for example, speakerphone, iPad, Skype, WebEx, Telepresence, etc.):
   _____

6. Were you able to hear everyone who spoke at the meeting (members of the body and members of the public)?

Poor				Excellent
1	2	3	4	5

   COMMENTS_____

7. How easy was it for you to obtain agenda materials for this meeting?

Easy				Difficult
1	2	3	4	5

   COMMENTS_____

8. Could you hear/understand what the speakers said or did static, interruption, or any other technological problems interfere?

Easy				Difficult
1	2	3	4	5

   COMMENTS_____

9. If the meeting used audio/visual technology, were you able to see all the people who spoke?

Poorly				Clearly
1	2	3	4	5

   COMMENTS_____

10. If there were any presentations (PowerPoint, etc.), were you able to hear and see them?

Poorly				Clearly
1	2	3	4	5

    COMMENTS_____

11. Were the members as attentive and did they participate as much as you would have expected?

Less				More
1	2	3	4	5

COMMENTS_____

12. Were there differences you noticed in how the members interacted?

With the other members present:

Very Different				No Difference
1	2	3	4	5

With members participating from other locations:

Very Different				No Difference
1	2	3	4	5

With the public:

Very Different				No Difference
1	2	3	4	5

COMMENTS_____

13. Did you feel the technology was a help or a hindrance?

Hindered				Helped
1	2	3	4	5

COMMENTS_____

14. How would you rate the overall quality of this meeting?

Poor				Excellent
1	2	3	4	5

COMMENTS_____

THANK YOU.

Please send your completed form by mail, facsimile, or electronic mail to the FOIA Council using the following contact information: Virginia Freedom of Information Advisory Council General Assembly Building, Second Floor 201 North 9th Street, Richmond, Virginia 23219
foiacouncil@dls.virginia.gov/Fax: 804-371-8705/Tele: 866-448-410

Virginia Medicaid Pharmacy & Therapeutics Committee Meeting

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

September 14, 2021

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

Brand Drugs

- KLOXXADO®(*Opiate Dependence Treatments*) *(Closed Class)*
- PLEGRIDY®, PONVORY™ (*Multiple Sclerosis Agents*)
- QELBREE® (*Stimulants and Related Agents*)

KLOXXADO®(Opiate Dependence Treatments)
(Closed Class)

KLOXXADO®(naloxone hydrochloride) nasal spray

- A higher dose naloxone nasal spray that delivers 8 mg to treat opioid overdose.
- It was approved through a 505(b)(2) NDA.
- Naloxone nasal spray was previously only approved in 2mg and 4mg products. (April 2021)

PLEGRIDY® (Multiple Sclerosis Agents)

PLEGRIDY® (peginterferon beta-1a) injection, for subcutaneous or intramuscular use

- An interferon beta 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.
- Approved as an intramuscular pre-filled syringe in the same dosage as the subcutaneous formulation (125 mcg/0.5 mL every 14 days).
- The most common adverse reactions in clinical trials were injection site erythema, influenza-like illness, pyrexia, headache, myalgia, chills, injection site pain, asthenia, injection site pruritus, and arthralgia
- Patients may self-administer the IM injection with proper training.
- Switching between the IM and SQ routes of administration has not been studied, however the need for repeat dose titration is not expected. (February 2021)

PONVORY™ (Multiple Sclerosis Agents)

PONVORY™ (ponesimod) tablets

- A sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.
- The maintenance dose is 20 mg orally once daily following an initial titration.
- First-dose monitoring is recommended in patients with certain preexisting cardiac conditions.
- Prior to initiating therapy with Ponvory several patient evaluations are recommended including complete blood count, ophthalmic evaluation, cardiac evaluation, vaccination history, liver function tests, and a review of current and prior medications.
- Contraindications include a recent cardiac event or presence of second- or third-degree AV block or sick sinus syndrome without a pacemaker.
- Warnings include risk of infection, bradyarrhythmia, liver injury, fetal risk, increased blood pressure, cutaneous malignancies, and macular edema.
- The most commonly reported adverse reactions were upper respiratory infection, elevated hepatic transaminases, and hypertension. (March 2021)

QELBREE® (Stimulants and Related Agents)

QELBREE® (viloxazine)

- A selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
- For patients 6 to 11 years of age, the recommended starting dose is 100 mg once daily which can be titrated in increments of 100 mg weekly to the maximum dose of 400 mg.
- For pediatric patients 12 to 17 years, the recommended starting dose is 200 mg daily and can be increased to the maximum dose of 400 mg after 1 week.
- There is a boxed warning for suicidal thoughts and behavior.
- Qelbree is contraindicated in patients receiving an MAOI and concomitant administration of sensitive CYP1A2 substrates.
- Warnings include elevations in blood pressure and heart rate, activation of mania or hypomania, and somnolence.
- The most commonly reported adverse reactions were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability. (April 2021)

PDL Phase II – New Drug Review (Therapeutic Class)

Generic Drugs or New Dosage Forms

- *(Acne Agents, Topical)*
  - tazarotene (generic for Fabior®)
- *(Cytokine and CAM Antagonists)*
  - Skyrizi™ Pen
- *(Steroids, Topical Very High)*
  - Clobetex® Kit

PDL Phase I – Annual Review
Therapeutic Classes with Updates

Antibiotics, Vaginal

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Cleocin® ovules (clindamycin)	*Cleocin® cream (clindamycin)*
Clindesse® cream (clindamycin)	*clindamycin cream*
metronidazole gel (generic for MetroGel®/Vandazole®)	*MetroGel-Vaginal® (metronidazole)*
Nuvessa® gel (metronidazole)	
Vandazole® gel (metronidazole)	

- Vandazole (metronidazole) is now approved for the treatment of bacterial vaginosis is post-menarchal females.

- The previous indication was for the treatment of bacterial vaginosis in non-pregnant women.
  - The indication no longer excludes pregnant women. (February 2021)

Human Immunodeficiency Virus (HIV) Agents (Closed Class)

FDA-APPROVED INDICATIONS

Drug	Manufacturer	Indication(s)
Attachment Inhibitor		
fostemsavir (Rukobia)[1]	ViiV	Treatment of HIV-1 infection for use in combination with other antiretrovirals in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
CCR5 Antagonist		
maraviroc (Selzentry®), *MVC*[2]	ViiV	Combination antiretroviral treatment of adults and pediatric patients weighing ≥ 2 kg infected with only CCR5-tropic HIV-1
Fusion Inhibitor		
enfuvirtide (Fuzeon®), *T20* or *ENF*[3]	Genentech	Treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy in combination with other antiretrovirals
Integrase Strand Transfer Inhibitors (INSTIs)		
dolutegravir (Tivicay®, Tivicay PD®), *DTG*[4]	ViiV	Tivicay and Tivicay PD: In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged ≥ 4 weeks and weighing ≥ 3 kg Tivicay *only*: In combination with rilpivirine as a complete regimen to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral components
raltegravir (Isentress®, Isentress HD), *RAL*[5]	Merck	In combination with other antiretroviral agents for the treatment of HIV-1 infection in patients weighing ≥ 2 kg*
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
doravirine (Pifeltro™), *DOR*[6]	Merck	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine
efavirenz (Sustiva®), *EFV*[7]	generic, Bristol-Myers Squibb	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients ≥ 3 months of age who weigh ≥ 3.5 kg
etravirine (Intelence®), *ETR*[8]	Janssen	In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients ≥ 2 years old

* Raltegravir (Isentress) chewable tablet is only indicated for patients weighing ≥ 3 kg. The suspension is only indicated for children from birth who weigh 2 kg to ≤ 20 kg. The HD tablet is indicated for adults and pediatric patients weighing ≤ 40 kg.

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) *(continued)*		
nevirapine‡ (Viramune®), *NVP*[9]	generic, Boehringer Ingelheim	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and in pediatric patients ≥ 15 days old
nevirapine extended-release (Viramune® XR), *NVP*[10]	generic, Boehringer Ingelheim	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and in children ≥ 6 years of age with a BSA ≥ 1.17 m^2
rilpivirine (Edurant®), *RPV*[11]	Janssen	In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients ≥ 12 years of age with HIV-1 RNA ≤ 100,000 copies/mL In combination with cabotegravir (Vocabria), for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
abacavir (Ziagen®), *ABC*[12]	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection
didanosine§ (Videx®, Videx EC®), *ddI*[13,14]	generic, Bristol-Myers Squibb	In combination with other antiretroviral agents for the treatment of HIV-1 infection
emtricitabine (Emtriva®), *FTC*[15]	Cipla, Gilead	In combination with other antiretroviral agents for the treatment of HIV-1 infection
lamivudine (Epivir®), *3TC*[16]	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection *Limitation of Use:* The dosage of this product is for HIV and not for hepatitis B virus (HBV)
stavudine¶, *d4t*[17]	generic	In combination with other antiretroviral agents for the treatment of HIV-1 infection
zidovudine (Retrovir®), *AZT*[18]	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection; Prevention of maternal-fetal HIV-1 transmission
Nucleotide Reverse Transcriptase Inhibitor (NRTI)		
tenofovir disoproxil fumarate (Viread®), *TDF*[19]	generic, Gilead	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients ≥ 2 years of age; Treatment of chronic hepatitis B (an infection with HBV) in adults ages ≥ 18 years and pediatric patients ≥ 2 years of age weighing ≥ 10 kg

‡ In May 2020, the FDA announced that Boehringer Ingelheim will discontinued Viramune 200 mg tablets; supply may be available until expiry. Generic versions of nevirapine IR and ER tablets and oral suspension are available.[20]

§ In February and March 2020, Bristol-Myers Squibb discontinued Videx 125 mg, 200 mg, 250 mg, and 400 mg capsules and Videx pediatric powder for oral solution; supply may be available until expiry. Generic versions of didanosine DR 250 mg and 400 mg capsules are available.

¶ All formulations of brand Zerit (stavudine) have been discontinued as of April 2020; generic versions remain.

Viiv discontinued delavirdine (Rescriptor®) 200 mg tablets in August 2020. No generics for delavirdine are available.

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Pharmacokinetic Enhancer		
cobicistat (Tybost®), *COBI* or *c*[21]	Gilead	In combination with atazanavir or darunavir to increase their systemic exposure once daily in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults and in pediatric patients weighing ≥ 35 kg co-administered with atazanavir or weighing ≥ 40 kg co-administered with darunavir
Protease Inhibitors (PIs)		
atazanavir (Reyataz®), *ATV*[22]	generic, Bristol-Myers Squibb	In combination with other antiretroviral agents for the treatment of HIV-1 infection; Treatment of HIV-1 infection in pediatric patients ≥ 3 years of age who weigh ≥ 5 kg
darunavir (Prezista®), *DRV*[23]	Janssen	Treatment of HIV-1 infection in adult patients, including pregnant women; Treatment of HIV-1 infection in pediatric patients ≥ 3 years of age who weigh ≥ 10 kg; *Limitation of use:* Prezista must be co-administered with ritonavir and with other antiretroviral agents
fosamprenavir (Lexiva®), *FPV*[24]	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection
indinavir‖ (Crixivan®), *IDV*[25]	Merck	In combination with other antiretroviral agents for the treatment of HIV-1 infection
nelfinavir (Viracept®), *NFV*[26]	ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection
ritonavir (Norvir®), *RTV* or *r*[27]	generic, Abbvie	In combination with other antiretroviral agents for the treatment of HIV-1 infection
saquinavir (Invirase®), *SQV*[28]	Genentech	Treatment of HIV-1 infection in combination with ritonavir and other antiretroviral agents in adults (≥ 16 years old)
tipranavir (Aptivus®), *TPV*[29]	Boehringer Ingelheim	Co-administered with ritonavir for combination antiretroviral treatment of HIV-1 infected patients who are treatment-experienced and infected with HIV-1 strains resistant to > 1 protease inhibitor; not indicated for use in treatment-naïve patients
Recombinant Monoclonal Antibody		
ibalizumab-uiyk (Trogarzo®)[30]	Thera	In combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen
Combination Products – Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTIs)		
abacavir/lamivudine (Epzicom®), *ABC/3TC*[31]	generic, ViiV	A co-formulated product containing 2 NRTIs used in combination with other antiretrovirals for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 25 kg
abacavir/lamivudine/ zidovudine (Trizivir®), *ABC/3TC/AZT*[32]	generic, ViiV	A co-formulated product containing 3 NRTIs used in combination with other antiretrovirals or alone for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 40 kg

‖ Merck will discontinue Crixivan (indinavir) 200 mg and 400 mg capsules on or near May 2020 and August 2020 for each strength, respectively; supply will remain available until product expiry. No generics are available.

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Combination Products – Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTIs) *(continued)*		
emtricitabine/tenofovir alafenamide (Descovy®), *FTC/TAF*[33]	Gilead	A combination product containing 2 NRTIs used in combination with other antiretroviral agents for the treatment for HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg or in combination with antiviral agents (other than protease inhibitors that require CYP3A inhibitors) for HIV-1 in pediatric patients weighing ≥ 25 kg to < 35 kg Indicated 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 for HIV-1 PrEP
emtricitabine/tenofovir disoproxil fumarate (Truvada®), *FTC/TDF*[34]	generic, Gilead	A co-formulated product containing 2 NRTIs used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 17 kg; Indicated in at-risk adults and adolescents weighing ≥ 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP
lamivudine/tenofovir disoproxil fumarate** (Cimduo®), *3TC/TDF*[35]	Mylan	A combination of 2 NRTIs indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 35 kg
lamivudine/tenofovir disoproxil fumarate (Temixys™), *3TC/TDF*[36]	Celltrion	A combination of 2 NRTIs indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 35 kg
lamivudine/zidovudine (Combivir®), *3TC/AZT*[37]	generic, ViiV	A co-formulated product containing 2 NRTIs used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 30 kg
Combination Products – Protease Inhibitors (PIs) or PIs + Pharmacokinetic Enhancer		
atazanavir/cobicistat (Evotaz®), *ATV/c*[38]	Bristol-Myers Squibb	A co-formulated product containing a PI and a pharmacokinetic enhancer used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg
darunavir/cobicistat (Prezcobix®), *DRV/c*[39]	Janssen	A co-formulated product containing a PI and a pharmacokinetic enhancer used in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults and pediatric patients weighing ≥ 40 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)
lopinavir/ritonavir (Kaletra®), *LPV/r*[40]	generic, Abbvie	A co-formulated product containing 2 PIs used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (≥ 14 days old)

** Cimduo (lamivudine/tenofovir disoproxil fumarate) was approved under a 505(b)(2) new drug application (NDA) pathway that allows at least some of the information submitted to the FDA to originate from research not conducted by or for the applicant [41,42]

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Combination Products – Multiple Classes		
bictegravir/emtricitabine/ tenofovir alafenamide (Biktarvy®), *BIC/FTC/TAF*[43]	Gilead	A co-formulated product containing 1 INSTI and 2 NRTIs approved as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 25 kg who are antiretroviral-naive or who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on their current, stable antiretroviral regimen for ≥ 3 months with no history of treatment failure and no known substitutions associated with resistance to its individual components
darunavir/cobicistat/ emtricitabine/tenofovir alafenamide (Symtuza®), *DRV/c/FTC/TAF*[44]	Janssen	A co-formulated product containing a PI, a CYP3A inhibitor, and 2 NRTIs indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 40 kg who have no prior antiretroviral treatment history or who are virologically suppressed (HIV-1 RNA < 50 copies/mL) while on stable antiretroviral therapy for ≥ 6 months and have no known substitutions associated with resistance to darunavir or tenofovir
dolutegravir/abacavir/ lamivudine (Triumeq®), *DTG/ABC/3TC*[45]	ViiV	A co-formulated product containing 1 INSTI and 2 NRTIs indicated for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 40 kg
dolutegravir/lamivudine (Dovato®), *DTG/3TC*[46]	ViiV	A co-formulated product containing 1 INSTI and 1 NRTI indicated as a complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato
dolutegravir/rilpivirine (Juluca®), *DTG/RPV*[47]	ViiV	A co-formulated product containing 1 INSTI and 1 NNRTI indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure and no known substitutions associated with resistance to its individual components
doravirine/lamivudine/ tenofovir disoproxil fumarate (Delstrigo™), *DOR/3TC/TDF*[48]	Merck	A co-formulated product containing 1 NNRTI and 2 NRTIs indicated as a complete regimen for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to Delstrigo
efavirenz/emtricitabine/ tenofovir disoproxil fumarate (Atripla®), EFV/FTC/*TDF*[49]	Gilead, Teva	A co-formulated product containing 2 NRTIs and 1 NNRTI used alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 40 kg
efavirenz/lamivudine/ tenofovir disoproxil fumarate (Symfi®), *EFV/3TC/TDF*[50]	Laurus, Mylan	A co-formulated product containing 1 NNRTI and 2 NRTIs indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 40 kg

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Combination Products – Multiple Classes *(continued)*		
efavirenz/lamivudine/ tenofovir disoproxil fumarate (Symfi Lo®), *EFV/3TC/TDF*[51]	Laurus, Mylan	A co-formulated product containing 1 NNRTI and 2 NRTIs indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 35 kg
elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide (TAF) (Genvoya®), *EVG/c/FTC/TAF*[52]	Gilead	A co-formulated product containing 1 INSTI, 1 pharmacokinetic enhancer, and 2 NRTIs for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure and no known substitutions associated with resistance to its components
elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate (Stribild®), *EVG/c/FTC/TDF*[53]	Gilead	A co-formulated product containing 1 INSTI, 1 pharmacokinetic enhancer, and 2 NRTIs as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients ≥ 12 years old and weighing ≥ 35 kg who are antiretroviral treatment-naïve or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for ≥ 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components
emtricitabine/rilpivirine/ tenofovir alafenamide (Odefsey®), *FTC/RPV/TAF*[54]	Gilead	A combination product containing 2 NRTIs and 1 NNRTI indicated for the treatment of HIV-1 infection in patients ≥ 35 kg as initial therapy in treatment-naïve patients with HIV-1 RNA ≤ 100,000 copies/mL or to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) for ≥ 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components
rilpivirine/emtricitabine/ tenofovir disoproxil fumarate (Complera®), *RPV/FTC/TDF*[55]	Gilead	A co-formulated product containing 2 NRTIs and 1 NNRTI used as a complete regimen for the treatment of HIV-1 infection in treatment-naïve patients ≥ 12 years old and weighing ≥ 35 kg with HIV-1 RNA ≤ 100,000 copies/mL at the start of therapy; As an alternate regimen for the treatment of HIV-1 infection in certain adult patients who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ritonavir-boosted PI regimen at start of therapy in order to replace their current antiretroviral treatment regimen

Human Immunodeficiency Virus (HIV) Agents (Closed Class) – (Continued)

- The International Antiviral Society – USA Panel has published 2020 recommendations on the use of antiretroviral drugs for treatment and prevention of HIV infection in adults.
  - The updated recommendations address new evidence since the prior publication of recommendations in 2018.
    - *For all individuals with HIV who have detectable viremia, antiretroviral therapy (ART) is recommended to be initiated as soon as possible.*
    - *The majority of patients are eligible for treatment initiation with either a 3- drug or 2-drug regimen, including an integrase strand transfer inhibitor.*
    - *Additionally, there are treatment options available for special populations of patients (e.g., pregnant women, patients with kidney, liver, or CV disease, those with opportunistic infections, those with healthcare access challenges).*
    - *Currently, switching therapy due to virological failure is generally rare; however, the recommendations for switching therapies due to convenience or for other reasons are addressed.*
    - *Preexposure prophylaxis with an oral regimen is recommended for individuals at risk for HIV. (November 2020)*

Bile Salts

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
ursodiol capsule and tablet	~~*Actigall® (ursodiol)*~~ *Chenodal® (chenodiol)* *Cholbam® (cholic acid)* *Ocaliva® (obeticholic acid)* *Urso® tab (ursodiol)* *Urso® Forte tab (ursodiol)*

- Allergan has made a business decision to discontinue Actigall 300 mg capsules.
  - Generic 300 mg capsules remain available as well as brand-name tablet formulations in other strengths (e.g., Urso Forte 500 mg tablet, Urso 250 mg tablet, ursodiol 250 mg tablet, and ursodiol 500 mg tablet). (January 2021)

Bile Salts - (Continued)

- FDA issued Drug Safety Communication regarding the use of obeticholic acid (Ocaliva) in patients with primary biliary cholangitis (PBC) with advanced cirrhosis of the liver due to the risk of serious hepatic failure, including a need for liver transplant.
    - Since its Accelerated Approval 5 years ago, the FDA has identified 25 cases of liver decompensation or failure, many of which in patients who had advanced cirrhosis prior to initiating obeticholic acid.
    - As a result, the FDA is requiring updated labeling, including a contraindication and warning to state that it should not be used in PBC patients with advanced cirrhosis. (May 2021)

Angiotensin Modulators II
(includes Direct Renin Inhibitors & Combination Products)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Direct Renin Inhibitors (includes combination)	
	aliskiren 150 & 300mg (generic for Tekturna) *Tekamlo® (aliskiren/amlodipine)* *Tekturna® (aliskiren)* *Tekturna HCT® (aliskiren/HCTZ)* *Twynsta® (telmisartan/amlodipine)* *telmisartan/amlodipine (generic for Twynsta)*

Angiotensin Modulators II
(includes Direct Renin Inhibitors & Combination Products) – (Continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Angiotensin Receptor Blockers	
Entresto™ **irbesartan** **losartan** **olmesartan** **valsartan**	*Atacand®* *Avapro®* *Benicar®* *candesartan* *Cozaar®* *Diovan®* *Edarbi®* ~~*eprosartan mesylate*~~ *Micardis®* *Teveten®*
Angiotensin Receptor Blockers + Diuretic Combinations	
irbesartan/HCTZ **losartan/HCTZ** **olmesartan/HCTZ** **valsartan/HCTZ**	*Atacand HCT®* *Avalide®* *Benicar HCT®* *candesartan/HCTZ* *Diovan HCT®* *Edarbyclor®* *Hyzaar®* *Micardis HCT®* *telmisartan/HCTZ* *Teveten HCT®*

Angiotensin Modulators II (includes Direct Renin Inhibitors & Combination Products) – (Continued)

- **Entresto** (sacubitril/valsartan) is now approved to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with chronic heart failure.
  - The benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
  - The previous indication specified use in NYHA Class II-IV and reduced ejection fraction. (February 2021)

- **Diovan** (valsartan) is now approved to treat hypertension in patients as young as 1 year of age.
  - It was previously approved for hypertension in patients as young as 6 years of age.
  - Diovan is also approved for select adults post-MI or with heart failure.
  - The package insert was updated with instructions on how to make a suspension using tablets in younger patients. (April 2021)

Angiotensin Modulators II
(includes Direct Renin Inhibitors & Combination Products) – (Continued)

- The American College of Cardiology (ACC) updated their 2017 Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment addressing 10 pivotal issues in heart failure with reduced ejection fraction (HFrEF) including:
  - (1) initiating, adding, or switching therapies to evidence-based treatments;
  - (2) optimal therapy given multiple drugs;
  - (3) when to refer to a specialist;
  - (4) addressing challenges of care coordination;
  - (5) improving medication adherence;
  - (6) specific patient cohorts;
  - (7) managing cost and access;
  - (8) managing complexity;
  - (9) managing comorbidities; and
  - (10) integrating palliative/hospice care.

- The update addresses expanded data since the 2017 publication on Angiotensin Receptor-Neprilysin Inhibitor (ARNIs) and Sodium-glucose transport protein 2 (SGLT2) inhibitors, resulting in updated/inclusion of target dosing and algorithms.

- ARNI's are recommended when HFrEF (EF ≤ 40%), NYHA class II–IV, and when administered in conjunction with a background of guideline-directed medical therapy (GDMT) in place of an ACEI or ARB.

- Ivabradine is recommended for HFrEF (EF ≤ 35%), NYHA class II or III, with a maximum dose of beta-blocker, and sinus rhythm with resting HR ≥ 70 bpm.

- SGLT2 inhibitors are recommended for HFrEF (EF ≤ 40%) with or without diabetes, NYHA class II–IV, and when administered in conjunction with background GDMT. (January 2021)

Angiotensin Modulators II
(includes Direct Renin Inhibitors & Combination Products) – (Continued)

- The Kidney Disease: Improving Global Outcomes (KDIGO) released new 2021 clinical practice guidelines for BP management in patients with CKD not receiving dialysis; updated from 2012 guidance.
  - The guidelines recommend target systolic BP < 120 mm Hg in most patients with CKD, with the exception of kidney transplant recipients and children.
  - Changes to the guidelines may increase the proportion of patients with CKD who are eligible for BP-lowering medications. (March 2021)

Angiotensin Modulators II
(includes Direct Renin Inhibitors & Combination Products) – (Continued)

- The American Heart Association (AHA) has published a Scientific Statement on the management of stage 1 hypertension in adults with a low 10-year risk for cardiovascular disease.

  - The statement is complementary to the 2017 Hypertension Clinical Practice Guidelines for the patient with untreated stage 1 hypertension (systolic BP/diastolic BP, 130–139/80–89 mm Hg) with a 10-year risk for atherosclerotic CVD <10% who do not meet the systolic BP/diastolic goal (< 130/80 mm Hg) following 6 months of guideline-recommended lifestyle therapy.

  - The statement provides evidence from sources outside of event-based randomized controlled trials and includes therapy options for clinicians to consider. (May 2021)

Lipotropics, Statins

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
HMG CoA Reductase Inhibitors and Combo (High Potency Statins)		
atorvastatin	*amlodipine/atorvastatin*	*simvastatin/ezetimibe*
rosuvastatin	*Caduet®*	*Vytorin®*
simvastatin	*Crestor®*	*Zocor®*
	Ezallor Sprinkle (rosuvastatin)	*Zypitamag™*
	Lipitor®	
	Liptruzet®	
	Livalo®	
	simvastatin sol (generic for Flolipid sol)	
HMG CoA Reductase Inhibitors and Combinations (Statins)		
lovastatin	~~*Advicor®*~~	
pravastatin	*Altoprev®*	
	fluvastatin	
	Lescol®and Lescol XL®	
	Mevacor®	
	Pravachol®	

Lipotropics, Statins - (Continued)

- FDA is requesting a class-wide removal of contraindications against use of statins in pregnant patients.
  - FDA stated benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, therefore contraindicating these drugs in all pregnant women is not appropriate.
  - FDA expects removing the contraindication will enable HCPs and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke.
  - This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke.
  - Data from published observational studies have not identified a drug-associated risk of major birth defects when controlling for other risks such as diabetes and are insufficient to determine if there is a drug-associated risk of miscarriage.
  - However, because statins decrease the body's ability to make cholesterol and possibly other substances, it is possible these medicines could harm an unborn baby when taken by a pregnant mother.
  - Patients should not breastfeed while on a statin since the medication may pass into the breast milk. (July 2021)

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Cholesterol Absorption Inhibitor (CAI) and /or Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor	
ezetimibe (generic for Zetia®)	*Nexletol™ (bempedoic acid)* *Nexlizet™ (bempedoic acid/ ezetimibe)* *Zetia® (ezetimibe)*
Omega 3 Fatty Acid Agents	
omega-3 acid ethyl esters **Omega-3 OTC**	*icosapent ethyl (generic Vascepa®)* *Lovaza® (omega 3 acid ethyl esters)* *Vascepa® (icosapent ethyl)*
Bile Acid Sequestrants	
cholestyramine powder reg & light **colestipol tab** **Prevalite®**	*Colestid® granule/packet/tab* *colesevelam tab and Pkt (generic Welchol)* *colestipol HCl granules* *Questran® powder/powder Light* *Welchol® pack/tab*
Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors	
	Praluent® *Repatha®*

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents) – (Continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Fibric Acid Derivatives	
fenofibrate (generic Tricor® 48mg, 145mg) **gemfibrozil**	*Antara®* *fenofibrate (generics for Antara® , Fenoglide® & Lipofen®)* *fenofibrate (generics for Triglide®)* *fenofibric acid* *Fenoglide®* *Fibricor®* *Lipofen®* *Lofibra®* *Lopid®* *Tricor®* *Triglide®* *Trilipix™*
Microsomal Triglyceride Transfer Protein Inhibitor	
	Juxtapid ™
Niacin Derivatives	
niacin ER	*Niaspan®* *Niacor®*

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents) – (Continued)

EVKEEZA™ (evinacumab-dgnb)

- An angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering treatments for adults and pediatric patients 12 years of age and older with homozygous familial hypercholesterolemia (HoFH).
- Evkeeza is supplied as a solution for injection in 345 mg/2.3mL (150 mg/mL) and 1,200 mg/8mL (150 mg/mL) in single dose vials.
- The recommended dose is 15mg/kg as an IV infusion over 60 minutes once monthly (every 4 weeks).
- The LDL-C should be evaluated as clinically appropriate, noting that the LDL-reducing effect can be assessed as early as 2 weeks following initiation.
- Warnings include embryo-fetal toxicity.
- The most commonly reported adverse reactions were nasopharyngitis, influenza-like illness, dizziness, rhinorrhea, and nausea. (February 2021)

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents) – (Continued)

PRALUENT® (alirocumab)

- Is now approved as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
  - *The recommended dosing in adults with HoFH is 150 mg subcutaneously every 2 weeks. (April 2021)*

- Already indicated:
  - *To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.*
  - *As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.*

Pulmonary Arterial Hypertension (PAH) Agents, Oral/Inhaled/Injectable

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Inhaled Prostacyclin Analogues	
Ventavis® (iloprost)	*Tyvaso® (treprostinil)*
Oral Endothelin Receptor Antagonist	
ambrisentan 5 & 10 mg (generic Letairis®) **Tracleer® tab (bosentan)**	*bosentan (generic Tracleer®)* *Letairis® 5 & 10 mg* *Opsumit® (macitentan)* *Tracleer® susp (bosentan)*
Phosphodiesterase 5 Inhibitors (PDE-5)	
Alyq (tadalafil 20mg) **sildenafil tab/susp** **tadalafil**	*Adcirca™ (tadalafil)* *Revatio® tab/susp/inj (sildenafil)*
Prostacyclin Vasodilator and Receptor Agonist	
	Orenitram™ (treprostinil) *Uptravi® (selexipag)*
Soluble Guanylate Cyclase Stimulators	
	Adempas® (riociguat)

Pulmonary Arterial Hypertension (PAH) Agents, Oral/Inhaled/Injectable – (Continued)

- **TYVASO® (treprostinil)**
  - Is now approved for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.
  - The effectiveness was established predominantly in patients with etiologies of:
    - *idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF)*
    - *combined pulmonary fibrosis and emphysema (CPFE) (25%)*
    - *WHO Group 3 connective tissue disease (22%).*
  - For this indication, the recommended dosing remains the same as with the previous approved indication for pulmonary arterial hypertension, as 3 breaths (18 mcg) per treatment session in 4 separate treatment sessions each day approximately 4 hours apart during waking hours.
  - The dosing can be increased by 3 breaths/session at 1-to-2-week intervals to a maintenance target of 9-12 breaths per session. (April 2021)

Anticonvulsants (Closed Class)

PREFERRED	NON-PREFERRED
Barbiturates	
phenobarbital elixir/tablet **primidone (generic for Mysoline®)**	*Mysoline® (primidone)*
Benzodiazepines	
clobazam (generic Onfi® tab) **clonazepam tablet (generic for Klonopin®)** **diazepam rectal & Device rectal** **Valtoco® spray (diazepam)**	*clonazepam ODT* *Diastat® rectal* *Diastat® AcuDial™ rectal* *Klonopin® (clonazepam)* *Nayzilam® spray (midazolam)* *Onfi® susp/tab* *Sympazan™ film (clobazam)*
Cannabidiol	
Epidiolex® (cannabidiol)	

Anticonvulsants – (Closed Class) - (Continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
Other Anticonvulsants		
Gabitril®	*Banzel® susp/tab*	*Potiga®*
lamotrigine tab	*Briviact®*	*Qudexy ™ XR*
lamotrigine chew tab	*Diacomit®*	*rufinamide (generic Banzel®)*
lamotrigine XR	*felbamate susp/tab*	*Sabril® powder pack/tab*
levetiracetam soln/tab	*Felbatol® susp/tab*	*Spritam®*
levetiracetam ER	*Fintepla®*	*tiagabine*
roweepra (generic version levetiracetam)	*Fycompa® susp/tab*	*Topamax® tab/sprinkle*
Vimpat® soln/tab	*Keppra® soln/tab*	*Trokendi™ XR*
topiramate tab/sprinkle cap	*Keppra® XR*	*vigabatrin (generic Sabril® tab)*
zonisamide cap	*Lamictal® XR*	*Xcopri®*
	Lamictal® ODT/ODT dose pk	*Zonegran®*
	Lamictal® tab/dose pk	
	Lamictal® XR dose pk	
	lamotrigine tab dose pk & ODT	

- **New generics for Banzel 200 mg tablet, 400 mg tablet, and 40mg/mL suspension**

Anticonvulsants – (Closed Class) - (Continued)

PREFERRED	NON-PREFERRED
Carbamazepine Derivatives	
carbamazepine chewable tab/susp/tab **carbamazepine ER** **carbamazepine XR** **oxcarbazepine susp & tab**	*Aptiom®* *Carbatrol®* *Equetro® cap* *Oxtellar™ XR* *Tegretol® susp/tab* *Tegretol® XR* *Trileptal® susp/tab* *vigabatrin powder pack*
Hydantoins	
phenytoin cap/chew tab/susp **phenytoin ext cap**	*Dilantin® cap* *Dilantin® Infatab, susp* *Peganone®* *Phenytek®*
Succinimides	
ethosuximide cap/syrup	*Celontin®* *Zarontin® cap/syrup*
Valproic Acid and Derivatives	
divalproex tab/sprinkle **divalproex ER** **valproic acid cap, sol**	*Depakene® cap/syrup* *Depakote® ER & sprinkle*

Anticonvulsants – (Closed Class) - (Continued)

Spritam® (levetiracetam)

- Now indicated for the treatment of partial-onset seizures (POS) in patients ≥ 4 years old weighing > 20 kg.
  - *It was previously indicated for POS as adjunctive therapy in patients with epilepsy ≥ 4 years old weighing > 20 kg.*

- It is also indicated as adjunctive therapy for the treatment of:
  - *Myoclonic seizures in patients ≥ 12 years old with juvenile myoclonic epilepsy*
  - *Primary generalized tonic-clonic seizures in patients ≥ 6 years with idiopathic generalized epilepsy.*

- Dosing is the same for POS when used as adjunctive therapy or monotherapy and is 500 mg twice daily, increased as needed/tolerated by 500 mg twice daily every 2 weeks to a maximum recommended dose of 1,500 mg twice daily for adults/pediatric patients ≥ 4 years weighing > 40 kg.

- For pediatric patients ≥ 4 years weighing 20 to 40 kg, the dosing is 250 mg twice daily, increased by 250 mg twice daily every 2 weeks to a maximum of 750 mg twice daily. (January 2021)

Anticonvulsants – (Closed Class) - (Continued)

- The FDA issued a Drug Safety Communication for lamotrigine (Lamictal) regarding a potential increased risk of arrhythmias in patients with heart disease as a result of reports of abnormal ECGs.

- The FDA will continue to evaluate and inform the public and healthcare professionals of their findings as more required in vitro studies are available.

- Healthcare providers should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. (April 2021)

Movement Disorders Agents (Closed Class)

FDA-APPROVED INDICATIONS

Drug	Manufacturer	Indication(s)
deutetrabenazine (Austedo®)[1]	Teva	Treatment of chorea associated with Huntington's disease; Treatment of tardive dyskinesia
tetrabenazine (Xenazine®)[2]	generic, Lundbeck	Treatment of chorea associated with Huntington's disease
valbenazine (Ingrezza®)[3]	Neurocrine Biosciences	Treatment of tardive dyskinesia

- There are various types of movement disorders, including parkinsonism, tremor, dystonia, dyskinesia, tics, chorea, and other involuntary movements.

- This class focuses on medications for the treatment of chorea associated with Huntington's disease and tardive dyskinesia.

Movement Disorders Agents (Closed Class) – (Continued)

SUMMARY

- All 3 agents within this class are vesicular monoamine transporter 2 (VMAT2) inhibitors used to treat select movement disorders in adults.

- Both deutetrabenazine (Austedo) and tetrabenazine (Xenazine) are approved for the treatment of chorea associated with Huntington's disease (HD).

- Due to its deuterated formulation, deutetrabenazine is dosed twice daily for doses ≥ 12 mg for HD, compared to tetrabenazine, which is dosed 2 or 3 times a day, depending on total daily dose.

- The optimal dose of each agent is determined individually for each patient based on reduction of chorea and patient tolerability; however, dose reductions are recommended in patients who are taking strong CYP2D6 inhibitors or are poor CYP2D6 metabolizers.

Movement Disorders Agents (Closed Class) – (Continued)

- Both tetrabenazine and deutetrabenazine are contraindicated in patients who are actively suicidal or in patients with untreated or inadequately treated depression, with hepatic impairment, taking monoamine oxidase inhibitors (MAOIs), or taking reserpine.

- Similarly, both agents carry a boxed warning for depression and suicidality as they may increase the risk of depression and suicidal thoughts and behavior in patients with Huntington's disease.

- Other warnings are similar between the 2 agents.

- The types of adverse effects are similar between deutetrabenazine and tetrabenazine, although the incidence of adverse effects appears higher with tetrabenazine.

Movement Disorders Agents (Closed Class) – (Continued)

- Deutetrabenazine and tetrabenazine have both demonstrated superiority over placebo but have not been compared head-to-head in controlled trials.
- The American Academy of Neurology (AAN) recommended tetrabenazine (up to 100 mg per day) and select medications off-label for chorea associated with HD in their 2012 guidelines.
- Deutetrabenazine has not been addressed in clinical practice guidelines; however, an update to the guidelines is in progress.
- Deutetrabenazine and valbenazine (Ingrezza) are the only FDA-approved medications for the treatment of tardive dyskinesia (TD).
- Early TD symptoms have been previously treated by reducing the dose or discontinuing the medication causing the symptoms.
- In 2013, the AAN published guidelines on the treatment of tardive syndromes, but deutetrabenazine and valbenazine have not been addressed by the AAN.

Movement Disorders Agents (Closed Class) – (Continued)

- While valbenazine carries fewer warnings than the other 2 agents within this class, like deutetrabenazine and tetrabenazine, it has warnings for somnolence and QT prolongation.

- Adverse effects are similar to the other VMAT2 inhibitors in this class but, like deutetrabenazine, the incidence of the adverse effects appears lower with valbenazine compared to tetrabenazine.

- Valbenazine is dosed once daily and deutetrabenazine is dosed twice daily for TD.

  – *A dosage reduction is required in select patients using these medications (e.g., hepatic impairment, hepatic metabolism status).*

  – *Both agents have demonstrated superiority over placebo in key clinical trials, but they have not been compared to each other or to other treatment strategies for TD (e.g., short-term clonazepam, causative medication adjustment).*

Immunomodulators, Atopic Dermatitis – (Closed Class)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Elidel®	*Eucrisa™* *Dupixent®* *pimecrolimus (generic for Elidel)* *Protopic®* *tacrolimus*

- Dupixent® (dupilumab) is approved as 200 mg/1.14 mL in a single-dose pre-filled pen for use in patients ≥ 12 years of age.
    - Dupixent was already available in a 200 mg/1.14 mL pre-filled syringe. (June 2021)

Hereditary Angioedema (HAE) Agents

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Berinert® (c1 inhibitor, human) **Cinryze™ (c1 inhibitor, human)** **Kalbitor® (ecallantide)**	*Firazyr® (icatibant)* *Haegarda® (c1 esterase inhibitor, human)* *icatibant (generic for Firazyr®)* *Orladeyo™ (berotralstat)* *Ruconest® (c1 esterase inhibitor, recombinant)* *Takhzyro™ (lanadelumab)*

- Haegarda is now approved for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in pediatric patients 6 years of age and older.
    - It was previously approved for this indication in adults and adolescents.
- The recommended dose is 60 IU/kg of bodyweight administered by subcutaneous injection twice weekly (every 3 or 4 days) for all patients.
- Haegarda can be self-administered or caregiver-administered following reconstitution. (October 2020)

Hereditary Angioedema (HAE) Agents – (Continued)

- **Orladeyo (berotralstat)**
  - Is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients ≥ 12 years old.
  - Its safety and effectiveness for the treatment of acute attacks have not been established; it should not be used for acute HAE attacks.
  - The recommended dose is 150mg once daily with food with recommended dose adjustments for hepatic impairment, drug interactions and adverse events.
  - Warnings include an increase in QT prolongation at doses exceeding 150mg daily.
  - The most frequently reported adverse reactions were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease. (December 2020)

Bladder Relaxants

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
oxybutynin tab/syrup **oxybutynin ER** **solifenacin** **Toviaz™**	*darifenacin ER (generic Enablex®)* *Detrol® & Detrol® LA* *Ditropan® & Ditropan® XL* *flavoxate* *Gelnique™ gel/gel Pump* *Gemtesa®* *Myrbetriq™* *Oxytrol® transdermal includes OTC* *Sanctura XR* *trospium IR & ER* *tolterodine IR & ER* *VESIcare®*

Bladder Relaxants – (Continued)

- **Gemtesa (vibegron)**
  - Is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency in adults.
  - It is available as a 75mg tablet, and the recommended dosage is 75mg orally once daily swallowed whole with water or crushed and mixed with applesauce.
  - There is a warning regarding the risk of urinary retention especially in patients with bladder outlet obstruction or with drug interactions.
  - The most commonly reported adverse reactions were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection. (December 2020)

Bladder Relaxants – (Continued)

- **Myrbetriq (mirabegron)** is now indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 3 years of age and older.
    - It was previously approved for use in adults only with overactive bladder.
- A new formulation is available for use in this younger population, Myrbetriq granules.
- The granules are an extended-release oral suspension in an 8 mg/mL strength following reconstitution.
- For patients weighing 35 kg or more, the recommended dose is 25 mg once daily with the option to increase the dose to 50 mg once daily after 4 to 8 weeks.
- If the granules are used, the dose is 48 mg (6mL) once daily with the option to increase the dose to 80 mg (10 mL) once daily after 4 to 8 weeks.
- The formulations are not interchangeable. (April 2021)

Bladder Relaxants – (Continued)

- **Toviaz (fesoterodine)** is now approved for the treatment of neurogenic detrusor overactivity in pediatric patients ≥ 6 years of age and ≥ 25 kg.

    - It was previously only approved for the treatment of overactive bladder in adults.

- For the new indication, the recommended dose is 4 mg once daily (maximum of 8 mg/day if needed) in patients 25 – 35 kg and 8 mg once daily in patients > 35 kg after a week of 4 mg/day. (June 2021)

Ophthalmics for Allergic Conjunctivitis

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Antihistamines	
Alaway OTC® **ketotifen fumerate** **olopatadine (generic Patanol & Pataday)** **~~Pazeo®~~** **Zaditor® OTC**	*bepotastine (generic Bepreve®)* *Bepreve®* *Elestat®* *epinastine 0.05% eye drops* *Ilevro™ 0.3%* *Lastacaft®* *Optivar®* *Patanol® Rx and OTC* *Pataday® Rx and OTC* *Zerviate ™*
Mast Cell Stabilizers	
cromolyn sodium	*Alocril®* *Alomide®*

- Novartis will discontinue the manufacture of Pazeo.
  - Pazeo has been replaced by OTC Pataday Once Daily 0.7%. (May 2021)

Ophthalmic Antibiotics

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
bacitracin/polymyxin b sulfate oint **ciprofloxacin drops** **erythromycin** **gentamicin drops/oint** **moxifloxacin drops (generic Vigamox)** **ofloxacin drops** **polymyxin/trimethoprim** **tobramycin**	*AzaSite™ drops* *bacitracin* *Besivance® drops* *Bleph®-10* *Ciloxan® drops/oint* *Garamycin® drops/oint* *gatifloxacin 0.5% soln* *Ilotycin®* *levofloxacin drops* *moxifloxacin drops (generic Moxeza®)*	*~~Moxeza® drops~~* *Natacyn®* *neomycin/polymyxin/gramicidin* *neomycin/bacitracin/polymyxin oint* *Neosporin®* *Ocuflox®* *Polytrim®* *sulfacetamide oint/soln* *Tobrex® drops/oint* *Vigamox®* *Zymaxid®*

- Novartis has made a business decision to discontinue Moxeza ophthalmic solution.
  - Generic formulations are available. (July 2021)

Ophthalmic Anti-Inflammatory/Immunomodulators (Closed Class)

FDA-APPROVED INDICATIONS

Drug	Manufacturer	Indication
cyclosporine emulsion (Restasis®, Restasis Multidose®)[1,2]	Allergan	Increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca
cyclosporine solution* (Cequa™)[3]	Sun	Increase tear production in patients with keratoconjunctivitis sicca (dry eye)
lifitegrast (Xiidra®)[4]	Shire/Novartis	Treatment of signs and symptoms of dry eye disease in adults
loteprednol (Eysuvis™)[5]	Kala	Short-term (up to 14 days) treatment of dry eye disease signs and symptoms

* Cequa (cyclosporine) and Eysuvis (loteprednol) were approved under the United States (US) Food and Drug Administration (FDA) 505(b)(2) pathway that allows at least some data submitted for approval to be from studies not conducted by or for the applicant.[6, 7,8]

Ophthalmic Anti-Inflammatory/Immunomodulators (Closed Class) – (Continued)

SUMMARY

- **Dry eye disease (DED), also known as dry eye syndrome and keratoconjunctivitis sicca, is related to either decreased tear volume (aqueous tear deficiency) or rapid evaporative loss (evaporative tear deficiency) due to poor tear quality.**
  - **Both of these conditions may be present as well.**
- **Thus, the role in therapy, or indication, of lifitegrast (Xiidra) is highly similar to that of topical cyclosporine 0.05% emulsion (Restasis, Restasis Multidose) and cyclosporine 0.09% solution (Cequa).**
- **However, lifitegrast is approved for both the signs and symptoms of DED, while both cyclosporine formulations are approved to enhance tear production and cyclosporine 0.05% emulsion (Restasis, Restasis Multidose) is also indicated to treat inflammation associated with DED.**
- **On the other hand, the newer agent, loteprednol (Eysuvis) is an ocular corticosteroid approved specifically for the short-term (up to 2 weeks) treatment of the signs and symptoms of DED.**

Ophthalmic Anti-Inflammatory/Immunomodulators (Closed Class) – (Continued)

- **Significant adverse effects are similar between the 4 agents in this class and primarily include ocular burning, irritation, or pain upon instillation.**
- **Topical cyclosporine may take up to 4 to 6 weeks to demonstrate benefit.**
- **Published clinical trials of lifitegrast evaluated outcomes primarily at 12 weeks; it is unknown if a clinically significant improvement may occur sooner.**
- **In clinical trials, improvement in DED with loteprednol was reported at day 15.**
- **Clinical practice guidelines recommend topical cyclosporine or lifitegrast for moderate and severe dry eye syndrome, in addition to other treatment measures.**
- **Loteprednol (Eysuvis) was not available at the time of the clinical practice guidelines publishing.**

Bronchodilators, Long-Acting Beta Adrenergics

Long-Acting Beta Adrenergics (LABA) MDIs or Nebulizers	
PREFERRED: NO SA REQUIRED	**NON-PREFERRED: SA REQUIRED**
Foradil® **Serevent Diskus®**	*arformoterol (generic Brovana®)* *Arcapta® Neohaler* *Brovana®* *formoterol fumarate (generic Perforomist®)* *Perforomist®* *Striverdi® Respimat*

- Brovana is now available as generic. The authorized generic was previously launched. (June 2021)

- Perforomist is now available as generic. (June 2021)

Recommend that the class continue to be PDL Eligible

Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Inhaled Corticosteroids: Combination Products (Glucocorticoid and Long-Acting Beta Adrenergic)	
Advair® Diskus & HFA (salmeterol/fluticasone) **Asmanex Twisthaler (mometasone)** **Dulera® (mometasone/formoterol)** **Symbicort® (budesonide/formoterol)**	*AirDuo® Digihaler® (fluticasone/salmeterol)* *Airduo™ Respiclick (fluticasone/salmeterol)* *Breo® Ellipta™ (fluticasone/vilanterol)* *Breztri Aerosphere™ (budesonide/formoterol/glycopyrrolate)* *fluticasone/salmeterol (generic for Airduo™)* *fluticasone/salmeterol powder (generic for Advair Diskus)* *Trelegy® Ellipta (fluticasone/umeclidinium/vilanterol)* *Wixela® (fluticasone/salmeterol)*
Inhaled Corticosteroids: Nebulizer Solution	
budesonide neb solution (generic for Pulmicort®)	*Pulmicort Respules® (budesonide)*
Inhaled Corticosteroids: Metered Dose Inhalers	
Flovent Diskus® & HFA(fluticasone) **Pulmicort Flexhaler® (budesonide)**	*Aerospan™ (flunisolide)* *Alvesco® (ciclesonide)* *Armonair™ Respiclick® (fluticasone)* *Arnuity™ Ellipta® (fluticasone)* *Asmanex HFA® (mometasone)* *QVAR® & QVAR® Redihaler (beclomethasone)*

Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)– (Continued)

- **National Asthma Education and Prevention Program updated their 2007 asthma guidelines.**
  - Key recommendations for pharmacotherapy are organized by asthma severity in the following steps:
    - *There were no recommended changes in step 1 (intermittent asthma) therapy maintaining the recommendation for as-needed SABAs for rescue therapy.*
    - *In step 2 (mild persistent asthma), either daily low-dose ICS plus as-needed SABA therapy or as-needed concomitant ICS and SABA therapy are recommended.*
    - *Formoterol in combination with an ICS in a single inhaler (single maintenance and reliever therapy) is recommended as the preferred therapy for moderate persistent asthma in step 3 (low-dose ICS-formoterol therapy)*
    - *Step 4 (medium-dose ICS-formoterol therapy) for both daily and as-needed therapy.*
    - *Add-on LAMAs are recommended in individuals whose asthma is not controlled by ICS-formoterol therapy for step 5 (moderate-severe persistent asthma).*
    - *Subcutaneous immunotherapy is recommended as an adjunct to standard pharmacotherapy for individuals with symptoms and sensitization to specific allergens.*
    - *Sublingual immunotherapy is not recommended specifically for asthma. (December 2020)*

Intranasal Rhinitis (includes Antihistamines and Corticosteroids)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
Intranasal Antihistamines		
azelastine 0.1%	*Astepro® 0.15%* *olopatadine* *Patanase®*	
Nasal Corticosteroids		
fluticasone Rx	*azelastine/fluticasone nasal spray (generic for Dymista®)* *Beconase AQ®* *budesonide (generic for Rhinocort® Aqua)* *budesonide (generic Rhinocort® Allergy OTC)* *Children's QnasI™* *Clarispray OTC* *Dymista®* *Flonase®* *Flonase Sensimist (OTC)* *flunisolide* *fluticasone OTC*	*mometasone (generic Nasonex®)* *~~Nasonex®~~* *Omnaris®* *QnasI™* *Rhinocort Aqua®* *Rhinocort® Allergy OTC* *Sinuva®* *Ticanase®* *triamcinolone OTC* *triamcinolone acetonide* *Veramyst®* *Xhance™* *Zetonna™*

Intranasal Rhinitis (includes Antihistamines and Corticosteroids) – (Continued)

- Merck has made a business decision to discontinue Nasonex nasal spray. Generic products remain available. (June 2021)

- FDA approved azelastine HCl nasal spray 0.15% (Astepro Allergy) for OTC use for seasonal and perennial allergic rhinitis in adults and children ≥ 6 years of age.
    - This is considered a partial prescription to nonprescription switch because the 0.1% strength, which includes the perennial allergy indication for children 6 months to 6 years of age and seasonal allergy indication for children 2 to 6 years of age, will remain prescription based. (June 2021)