



ARIZONA

**HEALTH CARE COST
CONTAINMENT SYSTEM**

AHCCCS Pharmacy and Therapeutics Committee

October 7, 2026

Welcome and Introductions

- Suzi Berman, RPh, Pharmacy Director, AHCCCS

Minutes Review and Vote

- Minutes Review and Vote - P&T May 19, 2026

Drug Class Reviews

Classes for Review: Non-Supplemental Rebate Drug Classes

- Analgesics Narcotics, Short Acting
- Angiotensin Modulators
- Angiotensin Modulator Combinations
- Antifungals, Oral
- Antifungals, Topical
- Antihistamines, Minimally Sedating
- Antimigraine Agents, Triptans
- Calcium Channel Blockers
- Contraceptives
- Hypoglycemics, DPP4s
- Intranasal Rhinitis Agents
- Lipotropics, Statins
- Ophthalmics, Glaucoma Agents
- Phosphate Binders

Drug Class Reviews

Classes for Review: Supplemental Rebate Drug Classes

- HIV / AIDS
- Lipotropics, Other
- Potassium Binders
- Sickle Cell Anemia



Non-Supplemental Rebate Drug Class Review

Hind Douiki, Pharm.D.

Analgesics Narcotics, Short Acting



Analgesics Narcotics, Short Acting

Drug	Federal Schedule	Manufacturer	Indication(s)
butorphanol nasal spray ¹	CIV	generic	Management of pain when the use of an opioid analgesic is appropriate
codeine sulfate ²	CII	generic	Mild to moderately severe pain when use of an opioid analgesic is appropriate and for which alternative treatments are inadequate
codeine/acetaminophen ³	CIII	generic	Mild to moderate pain
codeine/butalbital/ acetaminophen/caffeine (Fioricet® with codeine) ⁴	CIII	generic, Actavis/Teva	Tension or muscle contraction headache
codeine/butalbital/aspirin/ caffeine (Ascomp with codeine) ^{5,6}	CIII	generic, Breckenridge	Tension or muscle contraction headache
codeine/carisoprodol/aspirin ⁷	CIII	Ingenus	Moderate pain and muscle spasm associated with acute, painful musculoskeletal conditions
dihydrocodeine bitartrate/ acetaminophen/caffeine (Trexix™) ⁸	CIII	Xspire, Wraser	Moderate to moderately severe pain
fentanyl buccal (Fentora®) ⁹	CII	Mayne*, Cephalon	Breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain
fentanyl transmucosal oral lozenge (Actiq®) ¹⁰	CII	Mallinckrodt, Teva	Breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain

Analgesics Narcotics, Short Acting

hydrocodone/acetaminophen solution (Lortab®) ¹¹	CII	generic, Akorn	Moderate to moderately severe pain
hydrocodone/acetaminophen tablet ^{12,13}	CII	generic	
hydrocodone/ibuprofen ¹⁴	CII	generic	Short-term management of acute pain
hydromorphone (Dilaudid®) ¹⁵	CII	generic, Rhodes	Management of pain in patients where an opioid analgesic is appropriate
levorphanol ¹⁶	CII	generic	Moderate to severe pain
meperidine ^{17,18}	CII	generic	Moderate to severe pain
morphine immediate release ¹⁹	CII	generic	Moderate to severe acute and chronic pain
morphine immediate release ^{20,21}	CII	West-Ward/ Hikma, Roxane/ West-Ward	Moderate to severe acute pain in adults; Moderate to severe acute pain in pediatrics ≥ 2 years of age (oral solution) or weighing ≥ 50 kg (tablets)
oxycodone immediate release (Oxaydo®) ²²	CII	Egalet/Zyla	Moderate to severe acute and chronic pain
oxycodone immediate-release (Roxybond™) ²³	CII	Protega	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

Analgesics Narcotics, Short Acting

FDA-Approved Indications (continued)

Drug	Federal Schedule	Manufacturer	Indication(s)
oxycodone immediate release (Roxicodone®) ^{24,25}	CII	generic, Mallinckrodt	Moderate to severe pain in adults
oxycodone/acetaminophen (Endocet®, Nalocet®, Percocet®, Primlev™, Prolate®) ^{26,27,28,29,30}	CII	generic, Qualitest/Par, Forte Bio-Pharma, Endo, Akrimax, Forte Bio-Pharma	Moderate to severe pain
oxymorphone immediate release ³¹	CII	generic	Moderate to severe acute pain
pentazocine/naloxone ³²	CIV	generic	Moderate to severe pain
tapentadol (Nucynta®) ^{33,34}	CII	Collegium	Acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients ≥ 6 years old with a body weight of ≥ 16 kg (solution only) and ≥ 40 kg (tablet)
tramadol ^{35,36}	CIV	generic	Management of moderate to moderately severe pain in adults
tramadol (Qdolo™)* ³⁷	CIV	generic, Athena	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
tramadol/acetaminophen ^{38,39}	CIV	generic	Short-term (≤ 5 days) treatment of acute pain
tramadol/celecoxib (Seglantis®) ⁴⁰	CIV	Kowa	Management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate

Analgesics Narcotics, Short Acting

- Data demonstrates that approximately 24.3% of adults report chronic pain in the U.S.
- Historically, data have suggested that pain may be undertreated, but newer estimates imply that opioid treatment for pain may be overutilized
- Nearly 80,000 (about 76%) of the 2023 overdose deaths involved opioids
- Inappropriate use of opioid analgesics is thought to have contributed to the national crisis of opioid-related morbidity, mortality, and misuse
- 2024 provisional data suggest that opioid-involved overdose death is projected to decrease by over 30%

Analgesics Narcotics, Short Acting

- The World Health Organization's (WHO) guidelines for cancer pain management for adults recommend an approach with consideration for the type of pain and response to therapy
- If pain occurs, they recommend prompt oral administration of drugs in the following order:
 1. Non-opioids (acetaminophen, Non-Steroidal Anti-Inflammatory drugs [NSAIDs])
 2. As necessary, mild opioids (codeine)
 3. Strong opioids, until the patient is free of pain
- Per the American Society of Clinical Oncology (ASCO), opioids are recommended to be offered to patients with moderate to severe pain related to cancer or active treatment unless a contraindication is present

Analgesics Narcotics, Short Acting

- NCCN guidelines recommend against the use of meperidine (due to CNS toxicity) and limited usefulness for cancer pain
- the Centers for Disease Control and Prevention (CDC) released guidelines for prescribing opioids for pain outside of sickle cell disease, cancer, palliative, and end-of-life care
- When opioid therapy is initiated for acute, subacute, or chronic pain, it should be started with immediate-release agents

Analgesics Narcotics, Short Acting

- The American College of Physicians (ACP) and the American Academy of Family Physicians (AAFP) guidelines suggest against treating non-low back, musculoskeletal injury acute pain with opioids, including tramadol
- the North American Spine Society (NASS) published evidence-based clinical guidelines suggest that use of opioid pain medications for treating low back pain be limited and restricted to a short duration

Analgesics Narcotics, Short Acting

- Per the ACP, opioids should only be considered in those who have failed the following therapies:
 1. Non-pharmacologic treatment
 2. An NSAID or skeletal muscle relaxant for acute or subacute low back pain
 3. NSAID as first-line pharmacologic therapy; tramadol or duloxetine as second-line therapy for chronic low back pain
- The American Society of Interventional Pain Physicians' (ASIPP) opioid prescribing guidelines for the management of patients with chronic, non-cancer pain recommend that all patients be screened for opioid abuse
- Also, providers should use urine drug testing and prescription drug monitoring programs to monitor for abuse

Analgesics Narcotics, Short Acting

- The Institute for Clinical and Economic Review (ICER) published a final report on abuse-deterrent formulation (ADF) opioids
- At the time of evaluation, evidence showing a reduction in abuse risk with abuse-deterrent formulations compared to non-abuse-deterrent formulations risk was insufficient
- Roxybond (oxycodone) is the only immediate release opioid to have been FDA approved as an abuse-deterrent formulation

Analgesics Narcotics, Short Acting

- Clinical guidelines do not recommend one opioid agent over another
- Pain management should be individualized, patient-centered, multimodal, and multidisciplinary
- Healthcare professionals and health systems should be aware of health inequities and provide appropriate communication and support for all persons
- All agents within this class are considered controlled substances
- They also contain a boxed warning regarding serious risks of misuse, abuse, addiction, overdose, and death as well as risks when combined with other central nervous system depressants

Analgesics Narcotics, Short Acting

Clinical/Product Updates:

- The FDA's modified Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) is fully implemented
- Requires participating manufacturers to provide free, pre-paid mail-back envelopes upon request to outpatient pharmacies and other dispensers
- Manufacture of Percocet 325 mg/2.5 mg, 325 mg/5 mg, 325 mg/7.5 mg, and 325 mg/10 mg tablets will be discontinued
- The FDA approved the first generic for Nucynta oral tablet (50 mg, 75 mg, 100 mg)

Angiotensin Modulators



Angiotensin Modulators – ACE Inhibitors

Drug	Manufacturer	HTN	CHF	Post-MI	Other Indications
ACE Inhibitors					
benazepril (Lotensin)	generic	X (Pediatrics age 6-16 yrs)	–	–	–
captopril (Capoten)	generic	X	X	X (in patients with LVD)	Diabetic Nephropathy in type 1 diabetes)
enalapril (Vasotec Epaned)	generic (tablets) Silvergate (oral solution)	X (Pediatrics age 1 month - 16 yrs)	X (or asymptomatic LVD) only tablets	–	–
fosinopril (Monopril)	generic	X (Pediatrics age 6-16 yrs)	X	–	–
lisinopril (Prinivil, Qbrelis, Zestril)	generic (tablets) Silvergate (oral solution)	X (Pediatrics age 6-16 yrs)	X	X (in hemodynamically stable patients)	–
moexipril (Univasc)	generic	X	–	–	–

KEY: HTN = hypertension, LVD = left ventricular dysfunction, CAD = coronary artery disease, MI = myocardial infarction, CHF = congestive heart failure

Angiotensin Modulators – ACE Inhibitors

Drug	Manufacturer	HTN	CHF	Post-MI	Other Indications
ACE Inhibitors					
perindopril (Aceon)	generic	X	–	–	In stable CAD, reduces risk of cardiovascular mortality and non-fatal MI
quinapril (Accupril)	generic	X	X	–	–
ramipril (Altace)	generic (capsules) King (tablets)	X	X (post-MI)	–	Reduction of risk of MI, stroke, and death from cardiovascular causes
trandolapril (Mavik)	generic	X	X (post-MI)	– (in patients with CHF or LVD)	–
Renin Inhibitors					
aliskiren (Tekturna)	Novartis	X	–	–	–

Angiotensin Modulators – ACE Inhibitors

Diuretic Combination Products

Drug	Manufacturer
ACE Inhibitors	
benazepril/HCTZ (Lotensin HCT)	generic
captopril/HCTZ (Capozide)	generic
enalapril/HCTZ (Vaseretic)	generic
fosinopril/HCTZ	generic
lisinopril/HCTZ (Prinzide, Zestoretic)	generic
moexipril/HCTZ (Uniretic)	generic
quinapril/HCTZ (Accuretic)	generic
Renin Inhibitor	
aliskiren/HCTZ (Tekturna HCT)	Novartis

Angiotensin Modulators - ARBs

FDA-Approved Indications

Drug	Manufacturer	Indication(s)
Angiotensin II Receptor Blockers: Single Agents		
azilsartan (Edarbi®)	Arbor/Azurity	<ul style="list-style-type: none">Hypertension
candesartan (Atacand®)	generic, Ani	<ul style="list-style-type: none">Hypertension (including ages 1 to < 17 years)Treatment of HF (LVEF $\leq$ 40%, NYHA II-IV) to reduce risk of CV death and reduce hospitalizations for HF (in addition to ACE inhibitors or when ACE inhibitors are not tolerated)
eprosartan	Mylan	<ul style="list-style-type: none">Hypertension
irbesartan (Avapro®)	generic, Sanofi-Aventis	<ul style="list-style-type: none">HypertensionNephropathy in patients with type 2 diabetes
losartan (Cozaar®)	generic, Organon	<ul style="list-style-type: none">Hypertension (including ages 6 to 16 years)Nephropathy in patients with type 2 diabetesReduce the risk of stroke in hypertensive patients with LVH (not in African American patients)
losartan oral suspension (Arbli®)	Scienture	<ul style="list-style-type: none">Hypertension (in adults and children > 6 years of age)Reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophyNephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and history of hypertension

Angiotensin Modulators - ARBs

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Angiotensin II Receptor Blockers: Single Agents		
olmesartan (Benicar®) ¹	generic, Cosette	<ul style="list-style-type: none">Hypertension
telmisartan (Micardis®)	generic, Boehringer Ingelheim	<ul style="list-style-type: none">Hypertension80 mg tablets only: risk reduction of myocardial infarction (MI), stroke, or death from CV causes in patients ≥ 55 years at high risk of developing major CV events who are unable to take ACE inhibitors
valsartan (Diovan®)	generic, Novartis	<ul style="list-style-type: none">Hypertension (in adults and children ≥ 1 year of age)Treatment of HF (NYHA II-IV) to reduce hospitalizations for HFReduction of CV mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following MI
valsartan oral solution	Lifsa	<ul style="list-style-type: none">Hypertension (in adults and children ≥ 6 years of age)Treatment of HF (NYHA II-IV) to reduce hospitalizations for HF in patients who are unable to swallow valsartan tabletsReduction of CV mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following MI who are unable to swallow valsartan tablets

Angiotensin Modulators - ARBs

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Angiotensin II Receptor Blockers: Combination Products		
azilsartan/chlorthalidone (Edarbyclor®)	Arbor/Azurity	<ul style="list-style-type: none">Hypertension (first-line therapy in patients requiring multiple agents)
candesartan/HCTZ (Atacand HCT®)	generic, Ani	<ul style="list-style-type: none">Hypertension
irbesartan/HCTZ (Avalide®)	generic, Sanofi-Aventis	<ul style="list-style-type: none">Hypertension (first-line therapy in patients requiring multiple agents)
losartan/HCTZ (Hyzaar®)	generic, Organon	<ul style="list-style-type: none">Hypertension (first-line therapy in <u>setting of</u> prompt BP reduction)Reduce the risk of stroke in hypertensive patients with LVH (not in African American patients)
olmesartan/HCTZ (Benicar HCT®)	generic, Cosette	<ul style="list-style-type: none">Hypertension

Angiotensin Modulators - ARBs

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Angiotensin II Receptor Blockers: Combination Products (<i>continued</i>)		
sacubitril/valsartan (Entresto®, Entresto® Sprinkle)	Novartis	<ul style="list-style-type: none">▪ Reduce the risk of <u>CV</u> death and hospitalization for HF in patients with chronic HF; its benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal; clinical judgment is needed in deciding whom to treat▪ Treatment of symptomatic HF with systemic left ventricular systolic dysfunction in pediatric patients ages ≥ 1 year
telmisartan/HCTZ (Micardis HCT®) ²	generic, Boehringer Ingelheim	<ul style="list-style-type: none">▪ Hypertension
valsartan/HCTZ (Diovan HCT®)	generic, Novartis	<ul style="list-style-type: none">▪ Hypertension (first-line therapy in patients requiring multiple agents)

ACE inhibitors = angiotensin converting enzyme inhibitors; CV = cardiovascular; HCTZ = hydrochlorothiazide; HF = heart failure; LVH = left ventricular hypertrophy; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association Classification

Angiotensin Modulators

- Approximately 119.9 million (48.1%) of adults in the U.S. have hypertension (HTN)
- About 59.2% of adults with high blood pressure are aware of having it
- Highest prevalence is among African American adults at 59.6%
- It is estimated that hypertension is controlled (<130/80 mm Hg) in only 20.7% to 22.5% of patients with the condition
- Hypertension is an independent risk factor for the development of cardiovascular disease (CVD)

Angiotensin Modulators

- According to the 2025 American College of Cardiology (ACC) and American Heart Association (AHA), first-line therapy recommendations for HTN include thiazide diuretics, dihydropyridine CCBs, and ACE inhibitors or ARBs
- Patients with stage 2 hypertension (SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg) should be initiated on a single-pill fixed-dose dual combination of two first-line agents from different classes
- Agent selection is race-neutral, focusing on patient risk profile and comorbidities

Angiotensin Modulators

- Per the JNC-8, in the non-African American population, initial treatment should include a thiazide-type diuretic, calcium channel blocker (CCB), angiotensin-converting enzyme (ACE) inhibitor, or ARB
- For African Americans, initial treatment should include a thiazide-type diuretic or CCB
- In patients with Chronic Kidney Disease (CKD), treatment should include an ACE inhibitor or ARB to improve kidney function
- If BP goal is not reached within 1 month of starting treatment, the dose should be increased or a second drug from another class should be added; a third drug can be added if needed

Angiotensin Modulators

- The ADA recommends initiation of pharmacologic therapy for patients with an office BP $\geq 130/80$ mm Hg
- Patients with an office BP $\geq 150/90$ mm Hg should be initiated on 2 medications (or a single-pill combination of drugs) which have been shown to reduce CV events in people with diabetes mellitus (DM)
- Treatment should include an ACE inhibitor or ARB, a CCB, and/or a thiazide-like diuretic

Angiotensin Modulators

- Patients with coronary artery disease (CAD) or albuminuria should be prescribed an ACE inhibitor or an ARB as first-line therapy
- Per the American Academy of Pediatrics (AAP), first line therapy options include an ACE inhibitor, ARB, long acting CCB, or thiazide diuretic for high blood pressure in children and adolescents
- According to the ACC, AHA, and Heart Failure Society of America (HFSA), patients with pre-HF (stage B) and with left ventricular ejection fraction (LVEF) $\leq 40\%$ should be placed on an ACE inhibitor to prevent symptoms and to reduce mortality

Angiotensin Modulators

- If a patient is intolerant to an ACE inhibitor and has a history of recent myocardial infarction (MI), an ARB should be used instead
- Patients with heart failure with reduced ejection fraction (HFrEF) and New York Heart Association (NYHA) class II to III symptoms are recommended to be placed on sacubitril/valsartan (Entresto) to reduce morbidity and mortality
- If treatment with an ARNI is not feasible, then an ACE inhibitor may be prescribed, or an ARB can be used if a patient is intolerant to an ACE inhibitor

Angiotensin Modulators

- Treatment options that are potentially beneficial for patients with HF with preserved ejection fraction (HF_pEF) with LVEF $\geq 50\%$ include SGLT2 inhibitors, mineralocorticoid receptor antagonists (MRAs), ARBs, and ARNI
- Per the ACC, an ARB may be used for patients who cannot take an ARNI due to cost or intolerance
- Guidelines by the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists (AACE), and ACC suggest that all patients with DM should receive an ACE inhibitor or ARB for the treatment of hypertension to reduce the risk of stroke and to delay the progression of diabetic nephropathy

Angiotensin Modulators

- In patients with type 1 diabetes, hypertension, and nephropathy, long-term treatment with ACE inhibitors has been shown to reduce albuminuria and protect kidney function
- In patients with type 2 DM who have microalbuminuria, ACE inhibitors have been shown to reduce the urinary albumin excretion rate and mean arterial blood pressure
- ACE inhibitors and ARBs have been shown to delay the progression of nephropathy in patients with type 1 and type 2 diabetes

Angiotensin Modulators

- ACE inhibitors have clearly been shown to prevent early death in diabetic patients
- Telmisartan (Micardis) and ramipril (Altace) were similar in reducing CV mortality in patients with vascular disease or high-risk DM
- The Kidney Disease Improving Global Outcomes (KDIGO) recommend the use of ARBs or other renin-angiotensin-system inhibitors for patients with CKD, diabetes, hypertension, and moderately to severely increased albuminuria

Angiotensin Modulators

- In the setting of acute MI, ACE inhibitors have been shown to reduce mortality rates even in those with normal left ventricular function
- ACE inhibitors should be started and continued indefinitely in all patients recovering from ST-elevation myocardial infarction (STEMI) or unstable angina (UA)/non-ST-elevation myocardial infarction (NSTEMI) with LVEF of $\leq 40\%$ and for those with hypertension, DM, or CKD
- ACE inhibitors are also considered a reasonable option in patients who are at lower risk
- ARBs are recommended in place of ACE inhibitors in those who are intolerant to ACE inhibitors

Angiotensin Modulators

- According to the Agency for Healthcare Research and Quality (AHRQ), ACE inhibitors and ARBs appear to have similar long-term effects on blood pressure among individuals with essential hypertension
- It is possible that aliskiren may be more effective than ACE inhibitors (ramipril), but no differences were found in studies when compared to an ARB (losartan)
- There is insufficient evidence to determine if there are any different effects of ACE inhibitors versus ARBs on mortality and major CV events

Angiotensin Modulators

- ACE inhibitors have been shown to have a greater risk of cough than ARBs and the direct renin inhibitor
- No significant difference in antihypertensive efficacy or adverse effect profiles among ACE inhibitor agents
- A network meta-analysis of ACE inhibitors for heart failure (HF) showed ramipril was associated with the lowest all-cause mortality
- In a study of HF patients, ramipril demonstrated lower mortality compared to enalapril and lisinopril

Angiotensin Modulators

- Another study suggested that enalapril might be the most effective ACE inhibitor for improving certain heart function metrics, such as LVEF and stroke volume
- Enalapril was also associated with a higher rate of cough and renal function decline
- Some research suggests trandolapril is more successful at lowering both systolic and diastolic blood pressure than other ACE inhibitors
- Limited data suggest that candesartan (Atacand), valsartan (Diovan), and irbesartan (Avapro) at higher dosages offer greater decreases in blood pressure than losartan (Cozaar)

Angiotensin Modulator Combinations



Angiotensin Modulator Combinations

FDA-Approved Indications

Drug	Manufacturer	Indication(s)
amlodipine/benazepril (Lotrel®) ¹	generic, Novartis	Hypertension (not as initial therapy)
amlodipine/olmesartan (Azor®) ²	generic, Cosette	<ul style="list-style-type: none"> Treatment of hypertension either alone or in combination with other agents Initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure (BP) goals
amlodipine/olmesartan/HCTZ (Tribenzor®) ³	generic, Cosette	Hypertension (not as initial therapy)
amlodipine/perindopril (Prestalia®) ⁴	Adhera	<ul style="list-style-type: none"> Treatment of hypertension for patients not adequately controlled on monotherapy Initial treatment of hypertension in patients who will likely require multiple medications for BP control
amlodipine/telmisartan ⁵	generic	<ul style="list-style-type: none"> Treatment of hypertension alone or in combination with other agents Initial treatment of hypertension in patients who will likely require multiple medications for BP control
amlodipine/valsartan (Exforge®) ⁶	generic, Novartis	<ul style="list-style-type: none"> Initial treatment of hypertension in patients who will likely require multiple medications for BP control Treatment of hypertension for patients not adequately controlled on monotherapy
amlodipine/valsartan/HCTZ (Exforge HCT®) ⁷	generic, Novartis	Hypertension (not as initial therapy)
verapamil sustained-release (SR)/trandolapril ⁸	Glenmark	Hypertension (not as initial therapy)

HCTZ = hydrochlorothiazide

Angiotensin Modulator Combinations

- These agents are a fixed-dose combination of 2 or 3 of the following:
 - An ARB or an ACE inhibitor; in combination with
 - A CCB, with or without the addition of a thiazide diuretic
- The combination of an angiotensin modulator with a CCB has been shown to be more effective than either agent alone for the treatment of hypertension
- The combination products appear similar in efficacy and safety

Antifungals, Oral



Antifungals, Oral

Class Overview - Product indications include*:

- Candidiasis (esophageal, oropharyngeal, and vaginal)
- Cryptococcal infections
- Tinea topical infections
- Onychomycosis
- Invasive aspergillosis

****Not inclusive of all product indications, all products differ in indication***

Antifungals, Oral

Class Overview:

- clotrimazole troche - (clotrimazole troche)
- fluconazole - (Diflucan, fluconazole)
- flucytosine - (Ancobon, flucytosine)
- griseofulvin suspension - (griseofulvin suspension)
- griseofulvin microsize - (griseofulvin microsize)
- griseofulvin ultramicrosize -

- ibrexafungerp - (Brexafemme)
- isavuconazonium - (Cresmba)
- itraconazole - (itraconazole, Onmel, Sporanox)
- itraconazole - (Tolsura)
- ketoconazole - (ketoconazole)
- miconazole - (Oravig)
- nystatin - (nystatin)
- posaconazole - (Noxafil)
- terbinafine - (terbinafine)
- voriconazole - (Vfend, voriconazole)

Antifungals, Oral

- Oral antifungal agents have different spectrums of activity and are FDA-approved to treat a variety of infections in both immunocompetent and immunocompromised patients
- Few trials have been performed to compare safety and efficacy profiles of the drugs
- Many of the agents carry boxed warnings related to adverse events and/or drug interactions
- After bacterial vaginal infections, Vulvovaginal Candidiasis (VVC) is the second most common type of vaginal infection in the U.S.

Antifungals, Oral

- It is estimated that treatment with azole antifungals provides relief of symptoms and negative cultures in 80% to 90% of patients with uncomplicated VVC
- Due to its excellent penetration into many tissues, fluconazole is an effective *Candida* treatment for a variety of infections, lacking concerns about pH-dependent absorption such as that seen with ketoconazole
- Effective therapy for oropharyngeal candidiasis includes fluconazole, itraconazole, ketoconazole, nystatin, and clotrimazole
- Voriconazole has been shown to have similar efficacy to fluconazole in the treatment of esophageal candidiasis; however, more adverse effects are reported with voriconazole

Antifungals, Oral

- Posaconazole oral suspension has an indication for treatment of oropharyngeal candidiasis when refractory to itraconazole and/or fluconazole
- Posaconazole delayed-release oral tablets are indicated to treat invasive aspergillosis
- Nystatin is used to treat intestinal candidiasis and may be used in infants and children
- Isavuconazonium, posaconazole, flucytosine, voriconazole, itraconazole, and fluconazole have indications for the treatment and/or prophylaxis of various serious fungal infections

Antifungals, Oral

- Tolsura (itraconazole) is not indicated for the treatment of onychomycosis
- Ketoconazole is no longer to be used as first-line therapy for any fungal infection
- Previously, ketoconazole was indicated for candidiasis, chronic mucocutaneous candidiasis, oral thrush, candiduria, and severe recalcitrant cutaneous dermatophyte infections not responding to topical or oral griseofulvin therapy
- These indications were removed due to the risk of hepatic toxicity

Antifungals, Oral

Clinical/Product Updates:

- FDA approved expanded indication for treatment of invasive aspergillosis to include:
 - Patients 2 to <13 years old who weigh ≥ 10 kg for Noxafil injection
 - Patients 2 to <13 years of age who weigh ≥ 40 kg for Noxafil delayed-release tablets
 - Patients ≥ 2 years old who weigh 10 to 40 kg for the Noxafil Powder Mix for delayed-release oral suspension
- FDA reported that manufacture of Sporanox 100 mg capsules will be discontinued; generics remain available

Antifungals, Topical



Antifungals, Topical

Class Overview - Product indications include*:

- Cutaneous Candidiasis
- Tinea Pedis
- Tinea Corporis
- Tinea Cruris
- Tenia Versicolor
- Topical Onychomycosis
- Seborrheic Dermatitis

****Not inclusive of all product indications, all products differ in indication***



Antifungals, Topical

Class Overview

- butenafine - (Mentax)
- butenafine - (butenafine [OTC], Lotrimin Ultra [OTC])
- ciclopirox **1%** - (Ciclodan Cream, Kit; ciclopirox cream; Loprox Cream, Gel, Suspension)
- ciclopirox 1% - (ciclopirox 1% shampoo, Loprox)
- ciclopirox 8% - (Ciclodan Solution, ciclopirox 8%)
- clotrimazole - (Alevazol [OTC], clotrimazole [OTC], Lotrimin AF [OTC], Micotrin AC[OTC], Mycozyl AC [OTC]), Votriza-AL® [OTC])
- clotrimazole/betamethasone - (clotrimazole/betamethasone)
- econazole cream - (econazole)

Antifungals, Topical

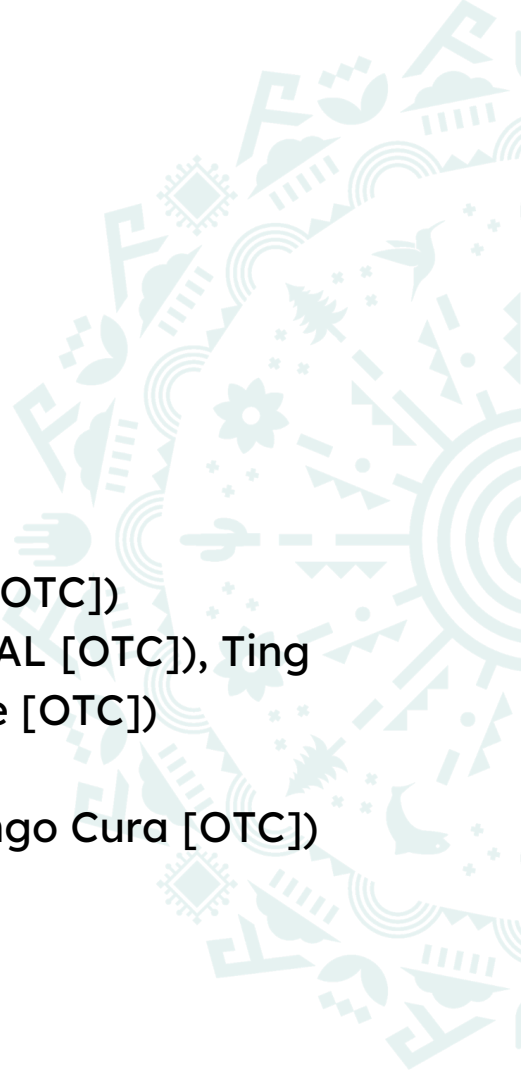
Class Overview:

- econazole foam - (Ecoza)
- efinaconazole - (Jublia)
- ketoconazole - (Extina, ketoconazole, Ketodan, Nizoral A-D 1% Shampoo [OTC], Xolegel)
- luliconazole - (Luzu)
- miconazole - (Azolen [OTC], Desenex [OTC] , Fungoid [OTC], Lotrimin AF Spray, [OTC], miconazole [OTC], Micotrin AP [OTC], Mycozyl AP [OTC], Zeasorb AF [OTC])
- miconazole/zinc oxide/white petrolatum - (Vusion)
- naftifine - (naftifine, Naftin)

Antifungals, Topical

Class Overview

- nystatin - (nystatin)
- nystatin/triamcinolone - (nystatin/triamcinolone)
- oxiconazole - (oxiconazole, Oxistat)
- sertaconazole - (Ertazco)
- sulconazole - (Exelderm)
- tavaborole - (Kerydin)
- terbinafine - (Lamisil [OTC], Lamisil AT [OTC], terbinafine [OTC])
- tolnaftate - (Fungoid-D [OTC], Micotrin AL [OTC], Mycozyl AL [OTC]), Ting [OTC], Lamisil AF Defense [OTC], Tinactin [OTC], tolnaftate [OTC])
- undecylenic acid - (Hongo Cura, Sponix Anti-Fungal [OTC])
- undecylenic acid/zinc undecylenic - (Fungi-Nail [OTC], Hongo Cura [OTC])



Antifungals, Topical

- Topical antifungal agents have different spectrums of activity and are FDA-approved to treat a variety of infections
- Topical agents may be formulated as creams, foams, gels, lacquers, lotions, ointments, powders, solutions and sprays
- Limited data are available regarding comparative efficacy in the treatment of the various fungal infections, including tinea cruris, tinea corporis, tinea pedis, and tinea versicolor

Antifungals, Topical

- Combination therapy (antifungal plus corticosteroid) can be considered when inflammation is present
- Data are also lacking in comparative efficacy for the treatment of seborrheic dermatitis
- Based on limited efficacy data, choice of therapy is mainly based on clinical judgment regarding prior treatments and complicating conditions, such as bacterial growth or intense inflammation

Antifungals, Topical

Clinical/Product Update:

- The manufacture of Exelderm 1% solution (5 mL & 30 mL) will be discontinued. Exelderm 1% cream remains available





Antihistamines, Minimally Sedating

Antihistamines, Minimally Sedating

FDA-Approved Indications

Drug	Rx/OTC	Manufacturer	Indication(s)
cetirizine capsules, tablets, oral liquid	Rx generic cetirizine oral liquid OTC generic chewable tablet, liquid gel, oral liquid, tablet Zyrtec® (all formulations)	<u>generic</u> , J&J Consumer	<ul style="list-style-type: none">▪ Temporary relief of symptoms due to hay fever or other respiratory allergies (sneezing; runny nose; itchy, watery eyes; itchy throat or nose) in adults and children ages ≥ 2 years▪ Relief of symptoms associated with seasonal AR due to allergens such as ragweed, grass, and tree pollens in adults and children <u>ages ≥ 2 years</u>▪ Relief of symptoms associated with perennial AR due to allergens such as dust mites, animal dander, and molds in adults and children <u>ages ≥ 6 months</u>▪ Treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU) in adults and children ages ≥ 6 months
cetirizine ODT (Zyrtec® Allergy ODT)	OTC	generic, J&J Consumer	<ul style="list-style-type: none">▪ Temporary relief of symptoms of upper respiratory allergies (sneezing; runny nose; itchy, watery eyes; itchy throat or nose) in adults and children ages ≥ 6 months▪ Relief of itching due to urticaria in patients in adults and children ages ≥ 6 months
cetirizine/pseudoephedrine (Zyrtec-D® OTC 12 Hour)	OTC	<u>generic</u> , J&J Consumer	<ul style="list-style-type: none">▪ Temporary relief of symptoms associated with sinusitis, allergic rhinitis, and other upper respiratory allergies (nasal congestion, sneezing; runny nose; itchy, watery eyes; itchy throat or nose) in adults and children ages ≥ 12 years

Antihistamines, Minimally Sedating

desloratadine tablet (Clarinet [®] , Clarinet Redi-Tabs [®])	Rx	generic, Organon	<ul style="list-style-type: none"> Relief of nasal and non-nasal symptoms of seasonal AR in patients ages ≥ 2 years Relief of nasal and non-nasal symptoms of perennial AR in patients <u>ages ≥ 6 months</u> Symptomatic relief of pruritus, reduction in the number of hives, and size of hives in patients with CIU ages ≥ 6 months
desloratadine ODT	Rx	generic	<ul style="list-style-type: none"> Relief of nasal and non-nasal symptoms of seasonal AR in patients ages ≥ 2 years Relief of nasal and non-nasal symptoms of perennial AR in patients ages ≥ 6 months
desloratadine/ pseudoephedrine (Clarinet-D [®] 12-Hour)	Rx	Organon	<ul style="list-style-type: none"> Relief of nasal and non-nasal symptoms of seasonal AR, including nasal congestion in adults and children ages ≥ 12 years
fexofenadine (Allegra [®])	OTC	generic, Chatterm Consumer	<ul style="list-style-type: none"> Relief of symptoms associated with hay fever or other upper respiratory allergies (sneezing; runny nose; itchy, watery eyes; itchy throat or nose) in adults and children ages ≥ 12 years
fexofenadine oral suspension	OTC	Generic	

Antihistamines, Minimally Sedating

Drug	Rx/OTC	Manufacturer	Indication(s)
fexofenadine ODT (Allegra ODT®)	OTC	Chattem Consumer	<ul style="list-style-type: none"> Relief of symptoms associated with hay fever or other upper respiratory allergies (sneezing; runny nose; itchy, watery eyes; itchy throat or nose) in adults and children ages ≥ 6 years
fexofenadine/pseudoephedrine (Allegra-D® 12 and 24 Hour)	OTC	generic, Chattem Consumer	<ul style="list-style-type: none"> Relief of symptoms associated with seasonal AR in adults and children ages ≥ 12 years
levocetirizine tablet, oral liquid	Rx	generic	<ul style="list-style-type: none"> Relief of symptoms associated with perennial AR in adults and children ages 6 months to 2 years Treatment of uncomplicated skin manifestations of CIU in adults and children ages ≥ 6 months
levocetirizine tablet (Xyzal® Allergy 24HR)	OTC	generic, Chattem Consumer	<ul style="list-style-type: none"> Temporary relief of runny nose, sneezing, itchy/watery eyes, and itching of the nose or throat due to hay fever or other respiratory allergies in patients 6 to 64 years of age
levocetirizine syrup (Children's Xyzal® Allergy 24HR; Xyzal Allergy 24HR)	OTC	Chattem Consumer	<ul style="list-style-type: none"> Temporary relief of runny nose, sneezing, itchy/watery eyes, and itching of the nose or throat due to hay fever or other respiratory allergies in patients ages ≥ 2 years
loratadine tablet, ODT, liquid, capsule (Alavert®, Claritin®, Claritin Redi-Tabs, Claritin® Liqui-Gels)	OTC	generic, Pfizer Consumer, Bayer/Schering-Plough	<ul style="list-style-type: none"> Temporary relief of symptoms due to hay fever or other respiratory allergies in adults and children <u>ages</u> ≥ 6 years
loratadine chewable tablet, ODT, syrup (Children's Claritin®, Claritin Chewable)	OTC	Bayer/Schering-Plough	<ul style="list-style-type: none"> Temporary relief of symptoms due to hay fever or other respiratory allergies in patients ages ≥ 2 years Treatment of CIU in patients ages ≥ 2 years
loratadine/pseudoephedrine (Claritin-D® 12 Hour, Claritin-D® 24 Hour)	OTC	generic, Foundation Consumer, Pfizer Consumer, Bayer/Schering-Plough	<ul style="list-style-type: none"> Temporary relief of symptoms (sinus nasal congestion, runny nose, sneezing, itchy nose, watery eyes) due to common cold, hay fever, or other respiratory allergies or sinusitis in adults and children ages ≥ 12 years

Rx = prescription required; OTC = over-the-counter; ODT = orally disintegrating tablet

Antihistamines, Minimally Sedating

- Allergic rhinitis (AR) affects 10% and 30% of adults and up to 40% of children in the U.S.
- AR is characterized by sneezing, itching of the eyes, nose, ears and palate, and rhinorrhea
- Symptoms develop when patients inhale airborne antigens to which they have previously been exposed and have made antibodies
- Seasonal AR generally occurs in the spring, summer, and early fall
- Perennial AR is an IgE-mediated reaction to allergens resulting in symptoms year-round and is usually caused by dust mites, pet hair, dander, mold, or cockroaches

Antihistamines, Minimally Sedating

- Non-allergic rhinitis usually affects adults and results in year-round symptoms
- Its causes can include strong odors, polluted air, smoke, and other irritants
- Oral antihistamines are particularly effective for severe rhinorrhea, sneezing, pruritus, and conjunctivitis associated with AR, although less effective for nasal congestion
- For patients with more significant nasal congestion, several of the minimally sedating antihistamines are available as combination dosage forms with a decongestant

Antihistamines, Minimally Sedating

- These minimally sedating (second-generation) antihistamines are generally considered before sedating (first-generation) antihistamines because they are associated with a lower incidence of side effects
- According to the American Academy of Allergy, Asthma, and Immunology (AAAAI), oral antihistamines are considered most effective for treatment for seasonal and perennial AR when used continuously
- Antihistamines, dosed when needed, can be an appropriate treatment option for episodic AR
- Oral antihistamines are as effective as intranasal corticosteroids for the treatment of ocular symptoms, but are less effective than intranasal corticosteroids for nasal congestion and AR symptoms

Antihistamines, Minimally Sedating

- Per the American Academy of Otolaryngology – Head and Neck Surgery, oral minimally sedating antihistamines are strongly recommended for patients with primary complaints of sneezing and itching
- Minimally sedating antihistamines are generally considered first-line therapy for Chronic Idiopathic Urticaria (CIU)
- Some studies indicate cetirizine may be more effective than loratadine at providing symptomatic relief
- Current data suggest the least likelihood of sedation is with fexofenadine or desloratadine

Antihistamines, Minimally Sedating

Clinical/Product Updates:

- Revisions to Drug Facts label for cetirizine include a warning about new onset pruritus that occurs after its discontinuation



Antimigraine Agents, Triptans



Antimigraine Agents, Triptans

Drug	Manufacturer	Indication(s)
almotriptan	generic	Acute treatment of migraine attacks with or without aura in adults and in adolescents 12 to 17 years of age whose attacks usually last 4 hours or more
eletriptan (Relpax®)	generic, Pfizer/Viatris	Acute treatment of migraine attacks with or without aura in adults
frovatriptan (Frova®)	generic, Endo	
naratriptan	generic	
rizatriptan (Maxalt®, Maxalt-MLT®)	generic, Merck Sharp & Dohme, Organon	Acute treatment of migraine attacks with or without aura in adults and in pediatric patients 6 to 17 years of age
rizatriptan/meloxicam (Symbravo®)	Axsome	Acute treatment of migraine with or without aura in adults

Antimigraine Agents, Triptans

Drug	Manufacturer	Indication(s)
sumatriptan (Imitrex®)	generic, GlaxoSmithKline	Acute treatment of migraine attacks with or without aura in adults (all formulations) Injection: Acute treatment of cluster headache episodes in adults
sumatriptan (Onzetra® Xsail®)	Curax	Acute treatment of migraine attacks with or without aura in adults
sumatriptan (Tosymra®)	Upsher-Smith	Acute treatment of migraine with or without aura in adults
sumatriptan (Zembrace® SymTouch®)	Promius/Upsher-Smith	Acute treatment of migraine with or without aura in adults
sumatriptan/naproxen (Treximet®)	generic, Curax	Acute treatment of migraine attacks with or without aura in those ≥ 12 years of age
zolmitriptan (Zomig®)	generic, Amneal	Acute treatment of migraine attacks with or without aura in adults

Antimigraine Agents, Triptans

- Migraines account for 10% to 20% of all headaches in adults and affect over 39 million men, women, and children in the U.S.
- Migraine headaches must be differentiated from regular tension-type headaches
- Key criteria for migraine diagnosis include an episodic headache lasting from 4 to 72 hours with at least two of the following:
 - Unilateral pain, throbbing, aggravation of pain upon moving, pain of moderate to severe intensity accompanied by nausea, vomiting, photophobia, or phonophobia
- Non-opioid analgesia with acetaminophen, NSAIDs, or caffeinated combinations
are considered first-line therapy for mild to moderate migraine pain

Antimigraine Agents, Triptans

- Migraine-specific agents (triptans, dihydroergotamine [DHE]) should be used in patients who experience moderate to severe migraine attacks
- Due to well-established efficacy, triptans have become the drugs of choice for treating acute migraine attacks
- The US Headache Consortium recognized that all of the triptans are effective agents for the acute treatment of migraine
- Data reviewed did not demonstrate that any specific triptan was superior to others
- Triptans appear to be equally safe

Antimigraine Agents, Triptans

- American College of Physicians (ACP) has published a guideline in 2025 on pharmacologic treatments for acute episodic migraine headache in the outpatient setting
- A triptan is *recommended* to be added to an NSAID to treat moderate to severe acute episodic migraine headache for non-pregnant adults who do not have a sufficient response to an NSAID (*strong recommendation; moderate-certainty evidence*)
- It is *suggested* to add a triptan to acetaminophen for the treatment of moderate to severe acute episodic migraine headache for nonpregnant adults who do not have a sufficient response to acetaminophen (*conditional recommendation; low-certainty evidence*)

Antimigraine Agents, Triptans

- For prevention of episodic migraine in non-pregnant adults in outpatient settings, this guideline suggests monotherapy with a beta blocker (e.g., metoprolol, propranolol), valproate, venlafaxine, or amitriptyline
- Patients who do not tolerate or have an inadequate response to these medications are suggested to be given monotherapy with a calcitonin gene-related peptide (CGRP) antagonist-gepant or CGRP monoclonal antibody
- Patients who do not respond to any of these therapies are suggested to be prescribed topiramate

Antimigraine Agents, Triptans

- Frovatriptan is established for short-term menstrually-associated migraine (MAM) prevention
- In addition to approval in adults, almotriptan, sumatriptan/naproxen, and zolmitriptan nasal spray are FDA-approved for use in patients 12 to 17 years old while rizatriptan is approved in patients 6 to 17 years old
- Non-oral routes of administration are available when nausea or vomiting present as significant components of migraine attacks

Antimigraine Agents, Triptans

Clinical/Product Updates:

- A business decision was made by the manufacturer to discontinue Frova. Generics remain available
- Rizatriptan film indication for acute treatment of migraine with or without aura was expanded to include patients 6 to 11 years of age
- In 2026, the American Academy of Neurology (AAN) and the American Headache Society (AHS) developed evidence-based recommendations for the pharmacologic prevention of episodic and chronic migraine in adults

Antimigraine Agents, Triptans

- For episodic migraine, options include atogepant, CGRP monoclonal antibodies (eptinezumab, erenumab, fremanezumab, galcanezumab), propranolol, topiramate, and valproate
- For chronic migraine, options include atogepant, eptinezumab, erenumab, fremanezumab, galcanezumab, topiramate, valproate, and OnabotulinumtoxinA
- For long-term safety, options include propranolol, topiramate, and OnabotulinumtoxinA
- For patients with high BMI or fibromyalgia, topiramate or amitriptyline can be offered, respectively
- For patients who are pregnant or lactating, divalproex sodium and topiramate should be avoided

Calcium Channel Blockers



Calcium Channel Blockers

Class Overview - Product indications include*:

- Hypertension
- Angina
- Vasospastic Angina
- Ventricular Rate Control
- Unstable Angina
- Coronary Artery Disease
- Subarachnoid hemorrhage

****Not inclusive of all product indications; all products differ in indication***



Calcium Channel Blockers

Class Overview: Dihydropyridines

- amlodipine - (amlodipine, Norvasc, Norliqva, Katerzia, Sdamlo)
- felodipine ER - (felodipine ER, Plendil)
- isradipine - (isradipine)
- Levamlodipine - (Conjupri)
- nicardipine - (Cardene, nicardipine)
- nicardipine SR - (Cardene SR)
- nifedipine - (nifedipine, Procardia)
- nifedipine ER, SA, SR - (Adalat CC, Afeditab CR, Nifediac CC, Nifedical XL nifedipine ER, SA, SR, Procardia XL)
- nimodipine - (nimodipine, Nymalize)

Calcium Channel Blockers

Class Overview: Dihydropyridines

- nisoldipine ER- (nisoldipine ER, Sular)

Class Overview: Non-dihydropyridines

- diltiazem - (Cardizem, diltiazem)
- diltiazem ER - (Cardizem LA, diltiazem ER, Matzim LA)
- diltiazem ER - (Cardizem CD; Cartia XT; diltiazem ER; Dilacor XR; Dilt CD; Taztia XT; Tiazac)



Calcium Channel Blockers

Class Overview: Non-dihydropyridines

- diltiazem ER - (Dilt XR, Diltia XT)
- verapamil - (Calan, verapamil)
- verapamil ER - (Covera-HS)
- verapamil ER - (verapamil ER, Verelan PM)
- verapamil SR - (Calan SR, Isoptin SR, verapamil ER, Verelan)



Calcium Channel Blockers

- Calcium channel blockers (CCBs) are widely used in the treatment of hypertension and angina pectoris
- Per the JNC-8, first-line therapy for hypertension in the non-African American population is a thiazide-type diuretic, a CCB, an ACE inhibitor, or an ARB
- They recommend a thiazide diuretic or CCB for African Americans
- The benefits of CCBs in controlling angina and hypertension have been clearly documented
- No CCB has demonstrated a clinical advantage over other CCBs in the treatment of hypertension
- Dihydropyridine CCBs may cause a baroreceptor-mediated reflex increase in heart rate

Calcium Channel Blockers

- Diltiazem decreases atrioventricular (AV) conduction and heart rate
- Verapamil decreases heart rate, slows AV nodal conduction to the greatest extent of the CCBs, and is useful for supraventricular tachyarrhythmias
- Short-acting nifedipine has been related to increased coronary mortality rates in patients with a history of MI and should not be used for the treatment of hypertension
- In patients with hypertension and a known risk factor for CAD, the ALLHAT study showed that chlorthalidone, amlodipine, and lisinopril had similar outcomes of combined fatal coronary heart disease (CHD) and nonfatal MI

Calcium Channel Blockers

- Many large trials enrolling patients with hypertension have demonstrated that CCBs have beneficial effects on composite cardiovascular outcomes or individual clinical outcomes
- However, most of the trials only demonstrated equivalence to the comparator antihypertensives rather than superiority

Calcium Channel Blockers

Clinical/Product Update:

- FDA approved etripamil (Cardamyst) indicated for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults

Contraceptives



Contraceptives, Oral

Products Listing

LABEL NAME	MANUFACTURER	DRUG TYPE
AFIRMELLE-28 TABLET	AUROBINDO PHARM	GEN
ALTAVERA-28 TABLET	XIROMED, LLC	GEN
ALYACEN 1-35 28 TABLET	GLENMARK PHARMA	GEN
ALYACEN 7-7-7-28 TABLET	GLENMARK PHARMA	GEN
AMETHIA 0.15-0.03-0.01 MG TAB	MAYNE PHARMA IN	GEN
AMETHYST 90-20 MCG TABLET	TEVA PHARM	BWG
APRI 28 DAY TABLET	TEVA USA	GEN
ARANELLE 28 TABLET	TEVA USA	GEN
ASHLYNA 0.15-0.03-0.01 MG TAB	GLENMARK PHARMA	GEN
AUBRA-28 TABLET	AFAXYS, INC.	GEN
AUBRA EQ-28 TABLET	AFAXYS, INC.	GEN
AUROVELA 1 MG-20 MCG TABLET	AUROBINDO PHARM	GEN
AUROVELA 21 1.5-30 TABLET	AUROBINDO PHARM	GEN
AUROVELA 24 FE 1 MG-20 MCG TAB	AUROBINDO PHARM	GEN
AUROVELA FE 1.5 MG-30 MCG TAB	AUROBINDO PHARM	GEN
AUROVELA FE 1-20 TABLET	AUROBINDO PHARM	GEN
AVERI 0.15-0.03 MG 28 DAY TAB	AVION PHARMACEU	SSB
AVIANE-28 TABLET	TEVA USA	GEN



Contraceptives, Oral

AYUNA-28 TABLET	AUROBINDO PHARM	GEN
AZURETTE 28 DAY TABLET	DR.REDDY'S LAB	GEN
BALCOLTRA TABLET	AVION PHARMACEU	SSB
BALZIVA 28 TABLET	TEVA USA	GEN
BEYAZ 28 TABLET	BAYER,PHARM DIV	SSB
BLISOVI 24 FE TABLET	LUPIN PHARMACEU	GEN
BLISOVI FE 1.5-30 TABLET	LUPIN PHARMACEU	GEN
BLISOVI FE 1-20 TABLET	LUPIN PHARMACEU	GEN
BRIELLYN 0.4 MG-0.035 MG TAB	GLENMARK PHARMA	GEN
CAMILA 0.35 MG TABLET	DR.REDDY'S LAB	GEN
CAMRESE 0.15-0.03-0.01 MG TAB	TEVA USA	GEN
CAMRESE LO TABLET	TEVA USA	GEN
CAZIENT 28 DAY TABLET	MAYNE PHARMA IN	GEN
CHARLOTTE 24 FE CHEWABLE TAB	GLENMARK PHARMA	GEN
CHATEAL EQ-28 TABLET	AFAXYS, INC.	GEN
CRYSELLE-28 TABLET	generic	GEN



Contraceptives, Oral

CYRED 28 DAY TABLET	AFAXYS, INC.	GEN
CYRED EQ 28 DAY TABLET	AFAXYS, INC.	BWG
DASETTA 1-35-28 TABLET	NORTHSTAR RX LL	GEN
DASETTA 7/7/7-28 TABLET	NORTHSTAR RX LL	GEN
DAYSEE 0.15-0.03-0.01 MG TAB	LUPIN PHARMACEU	GEN
DEBLITANE 0.35 MG TABLET	NORTHSTAR RX LL	GEN
DOLISHALE 90-20 MCG TABLET	INGENUS PHARMAC	GEN
DROSP-EE-LEVOMEF 3-0.02-0.451	generic	GEN
DROSP-EE-LEVOMEF 3-0.03-0.451	SANDOZ	GEN
ECONTRA EZ 1.5 MG TABLET	AFAXYS, INC.	GEN
ECONTRA ONE-STEP 1.5 MG TABLET	AFAXYS, INC.	GEN
ELINEST-28 TABLET	NORTHSTAR RX LL	GEN
ELLA 30 MG TABLET	HRA PHARMA AMER	BWG
EMZAHH 0.35 MG TABLET	AUROBINDO PHARM	GEN
ENPRESSE-28 TABLET	TEVA USA	SSB
ENSKYCE 28 TABLET	LUPIN PHARMACEU	GEN
ERRIN 0.35 MG TABLET	DR.REDDY'S LAB	GEN



Contraceptives, Oral

ESTARYLLA 0.25-0.035 MG TABLET	XIROMED, LLC	GEN
DROSPIRENONE-EE 3-0.02 MG TAB	generic	GEN
DROSPIRENONE-EE 3-0.03 MG TAB	generic	GEN
FALMINA-28 TABLET	NORTHSTAR RX LL	GEN
FEIRZA 1 MG-20 MCG TABLET	XIROMED, LLC	GEN
FEIRZA 1.5 MG-30 MCG TABLET	XIROMED, LLC	GEN
FEMLYV 1 MG-0.02 MG ODT	MILLICENT PHARM	SSB
FINZALA 1-0.02(24)-75 CHEW TAB	TEVA USA	BWG
GALBRIELA 0.8-0.025 MG CHEW TB	XIROMED, LLC	GEN
GEMMILY 1 MG-20 MCG CAPSULE	XIROMED, LLC	GEN
HAILEY 24 FE 1 MG-20 MCG TAB	GLENMARK PHARMA	GEN
HAILEY FE 1.5-30 TABLET	GLENMARK PHARMA	GEN
HAILEY FE 1-20 TABLET	GLENMARK PHARMA	GEN
HAILEY 21 1.5 MG-30 MCG TAB	GLENMARK PHARMA	GEN
HEATHER 0.35 MG TABLET	GLENMARK PHARMA	GEN
ICLEVIA 0.15 MG-0.03 MG TABLET	AUROBINDO PHARM	GEN
INCASSIA 0.35 MG TABLET	AUROBINDO PHARM	GEN



Contraceptives, Oral

INTROVALE 0.15-0.03 MG TABLET	XIROMED, LLC	GEN
ISIBLOOM 28 DAY TABLET	XIROMED, LLC	GEN
JAIMESS 0.15-0.03-0.01 MG TAB	XIROMED, LLC	GEN
JASMIEL 3 MG-0.02 MG TABLET	AFAXYS, INC.	GEN
JENCYCLA 0.35 MG TABLET	LUPIN PHARMACEU	GEN
JOLESSA 0.15 MG-0.03 MG TABLET	TEVA USA	BWG
JOYEAUX-28 TABLET	XIROMED, LLC	GEN
JULEBER 28 DAY TABLET	NORTHSTAR RX LL	GEN
JUNEL 1 MG-20 MCG TABLET	TEVA USA	GEN
JUNEL 1.5 MG-30 MCG TABLET	TEVA USA	GEN
JUNEL FE 1 MG-20 MCG TABLET	TEVA USA	GEN
JUNEL FE 1.5 MG-30 MCG TABLET	TEVA USA	GEN
JUNEL FE 24 TABLET	TEVA USA	GEN
KAITLIB FE 0.8-0.025MG CHEW TB	LUPIN PHARMACEU	GEN
KALLIGA 28 DAY TABLET	AUROBINDO PHARM	GEN
KARIVA 28 DAY TABLET	TEVA USA	GEN
KELNOR 1-35 28 TABLET	TEVA USA	SSB
KELNOR 1-35 28 TABLET	TEVA USA	GEN



Contraceptives, Oral

KURVELO-28 TABLET	LUPIN PHARMACEU	GEN
LARIN 1.5 MG-30 MCG TABLET	NORTHSTAR RX LL	GEN
LARIN 21 1-20 TABLET	NORTHSTAR RX LL	GEN
LARIN 24 FE 1 MG-20 MCG TABLET	NORTHSTAR RX LL	GEN
LARIN FE 1.5-30 TABLET	NORTHSTAR RX LL	GEN
LARIN FE 1-20 TABLET	NORTHSTAR RX LL	GEN
LESSINA-28 TABLET	TEVA USA	GEN
LEVONEST-28 TABLET	NORTHSTAR RX LL	GEN
LEVONORG-EE-FE BIS 0.1-0.02-36	ACELLA PHARMACE	GEN
LEVONORGESTREL 1.5 MG TABLET	generic	GEN
LEVONOR-ETH ESTRA 0.09-0.02 MG	GLENMARK PHARMA	GEN
LEVONOR-ETH ESTRAD 0.15-0.03	generic	GEN
LEVONOR-ETH ESTRAD 0.1-0.02 MG	generic	GEN
LEVONOR-ETH ESTRAD TRIPHASIC	LUPIN PHARMACEU	GEN
LO LOESTRIN FE 1-10 TABLET	ACTAVIS/ALLERGA	SSB
LOESTRIN 21 1.5-30 TABLET	TEVA WOMEN'S HE	BWG



Contraceptives, Oral

LOESTRIN 21 1-20 TABLET	TEVA WOMEN'S HE	BWG
LOESTRIN FE 1.5-30 TABLET	TEVA WOMEN'S HE	BWG
LOESTRIN FE 1-20 TABLET	TEVA WOMEN'S HE	BWG
LOJAIMIESS 0.1-0.02-0.01 TAB	XIROMED, LLC	GEN
LORYNA 3 MG-0.02 MG TABLET	XIROMED, LLC	GEN
LOW-OGESTREL-28 TABLET	MAYNE PHARMA IN	GEN
LO-ZUMANDIMINE 3 MG-0.02 MG TB	AUROBINDO PHARM	GEN
LUIZZA 1 MG-20 MCG TABLET	XIROMED, LLC	GEN
LUIZZA 1.5 MG-30 MCG TABLET	XIROMED, LLC	GEN
LYLEQ 0.35 MG TABLET	AFAXYS, INC.	GEN
LYZA 0.35 MG TABLET	AFAXYS, INC.	GEN
MARLISSA-28 TABLET	GLENMARK PHARMA	GEN
MELEYA 0.35 MG TABLET	XIROMED, LLC	GEN
MIBELAS 24 FE CHEWABLE TABLET	LUPIN PHARMACEU	GEN
MICROGESTIN 21 1.5-30 TAB	DR.REDDY'S LAB	GEN
MICROGESTIN 21 1-20 TABLET	DR.REDDY'S LAB	GEN
MICROGESTIN FE 1.5-30 TAB	DR.REDDY'S LAB	GEN
MICROGESTIN FE 1-20 TABLET	DR.REDDY'S LAB	GEN



Contraceptives, Oral

MILI 0.25-0.035 MG TABLET	AUROBINDO PHARM	GEN
MINZOYA-28 TABLET	LUPIN PHARMACEU	GEN
MONO-LINYAH 28 TABLET	NORTHSTAR RX LL	BWG
MY CHOICE 1.5 MG TABLET	SUN PHARMACEUTI	GEN
MY WAY 1.5 MG TABLET	LUPIN PHARMACEU	GEN
NATAZIA 28 TABLET	BAYER,PHARM DIV	SSB
NECON 0.5-35-28 TABLET	DR.REDDY'S LAB	GEN
NEW DAY 1.5 MG TABLET	NORTHSTAR RX LL	GEN
NEXTSTELLIS 3-14.2 MG TABLET	MAYNE PHARMA IN	SSB
NIKKI 3 MG-0.02 MG TABLET	LUPIN PHARMACEU	GEN
NORA-BE TABLET	TEVA USA	BWG
NORETHINDRONE 0.35 MG TABLET	generic	GEN
NORETHIND-ETH ESTRAD 1-0.02 MG	generic	GEN
NORETH-EE-FE 1-0.02(24)-75 CAP	GLENMARK PHARMA	GEN
NORETH-EE-FE 1-0.02(24)-75 CHW	XIROMED, LLC	GEN
NORG-ETHIN ESTRA 0.25-0.035 MG	generic	GEN



Contraceptives, Oral

NORG-EE 0.18-0.215-0.25/0.035	generic	GEN
NORTREL 0.5-35-28 TABLET	TEVA USA	GEN
NORTREL 1-35 21 TABLET	TEVA USA	GEN
NORTREL 1-35 28 TABLET	TEVA USA	GEN
NORTREL 7-7-7-28 TABLET	TEVA USA	GEN
NYLIA 1-35 28 TABLET	AUROBINDO PHARM	GEN
NYLIA 7-7-7-28 TABLET	AUROBINDO PHARM	GEN
OPCICON ONE-STEP 1.5 MG TABLET	SUN PHARMACEUTI	GEN
OPILL 0.075 MG TABLET	PERRIGO CO.	SSB
OPTION 2 1.5 MG TABLET	PERRIGO CO.	GEN
ORQUIDEA 0.35 MG TABLET	XIROMED, LLC	GEN
ORTHO TRI-CYCLEN 28 TABLET	JANSSEN PHARM.	BWG
ORTHO-NOVUM 7-7-7-28 TABLET	JANSSEN PHARM.	SSB
PHILITH 0.4-0.035 MG TABLET	NORTHSTAR RX LL	GEN
PIMTREA 28 DAY TABLET	NORTHSTAR RX LL	GEN
PORTIA-28 TABLET	TEVA USA	GEN
RECLIPSEN 28 DAY TABLET	TEVA USA	GEN



Contraceptives, Oral

RIVELSA TABLET	TEVA USA	GEN
ROSYRAH TABLET	XIROMED, LLC	GEN
SAFYRAL TABLET	BAYER,PHARM DIV	SSB
SETLAKIN 0.15 MG-0.03 MG TAB	NORTHSTAR RX LL	GEN
SHAROBEL 0.35 MG TABLET	NORTHSTAR RX LL	GEN
SIMLIYA 28 DAY TABLET	AUROBINDO PHARM	GEN
SIMPESSE 0.15-0.03-0.01 MG TAB	AUROBINDO PHARM	GEN
SLYND 4 MG TABLET	EXELTIS USA, IN	SSB
SPRINTEC 28 DAY TABLET	TEVA USA	GEN
SYEDA 28 TABLET	XIROMED, LLC	GEN
TARINA 24 FE 1 MG-20 MCG TAB	AFAXYS, INC.	GEN
TARINA FE 1-20 TABLET	AFAXYS, INC.	GEN
TARINA FE 1-20 EQ TABLET	AFAXYS, INC.	GEN
TAYTULLA 1 MG-20 MCG CAPSULE	ALLERGAN INC.	SSB
TILIA FE 28 TABLET	DR.REDDY'S LAB	GEN
TRI-ESTARYLLA TABLET	XIROMED, LLC	SSB
TRI-LEGEST FE-28 DAY TABLET	TEVA USA	GEN



Contraceptives, Oral

TRI-LINYAH TABLET	NORTHSTAR RX LL	BWG
TRI-LO-ESTARYLLA TABLET	XIROMED, LLC	GEN
TRI-LO-MARZIA TABLET	LUPIN PHARMACEU	GEN
TRI-LO-MILI TABLET	AUROBINDO PHARM	GEN
TRI-LO-SPRINTEC TABLET	TEVA USA	GEN
TRI-MILI 28 TABLET	AUROBINDO PHARM	GEN
TRI-SPRINTEC TABLET	TEVA USA	GEN
TRI-VYLIBRA 28 TABLET	AFAXYS, INC.	GEN
TRI-VYLIBRA LO TABLET	AFAXYS, INC.	GEN
TULANA 0.35 MG TABLET	AFAXYS, INC.	GEN
TURQOZ-28 TABLET	LUPIN PHARMACEU	GEN
TYBLUME 0.1-0.02 MG CHEW TAB	EXELTIS USA, IN	BWG
VALTYA 1 MG-35 MCG TABLET	XIROMED, LLC	GEN
VALTYA 1 MG-50 MCG TABLET	XIROMED, LLC	GEN
VELIVET 28 DAY TABLET	TEVA USA	GEN



Contraceptives, Oral

VESTURA 3 MG-0.02 MG TABLET	TEVA PHARM	GEN
VIENVA-28 TABLET	XIROMED, LLC	GEN
VIORELE 28 DAY TABLET	GLENMARK PHARMA	GEN
VOLNEA 0.15-0.02-0.01 MG TAB	XIROMED, LLC	GEN
VYFEMLA 0.4 MG-0.035 MG TABLET	LUPIN PHARMACEU	BWG
VYLIBRA 28 TABLET	AFAXYS, INC.	GEN
WERA 0.5/0.035 MG 28 TABLET	NORTHSTAR RX LL	GEN
WYMZYA FE 0.4-0.035 MG CHEW TB	LUPIN PHARMACEU	BWG
XARAH FE 1 MG/20-30-35 MCG TAB	XIROMED, LLC	GEN
XELRIA FE 0.4-0.035 MG CHEW TB	XIROMED, LLC	GEN
YASMIN 28 TABLET	BAYER,PHARM DIV	BWG
YAZ 28 TABLET	BAYER,PHARM DIV	BWG
YOUR CHOICE 1.5 MG TABLET	OHM LABS.	GEN
ZARAH TABLET	MAYNE PHARMA IN	GEN
ZOVIA 1-35 TABLET	DR.REDDY'S LAB	GEN
ZUMANDIMINE 3 MG-0.03 MG TAB	AUROBINDO PHARM	GEN



Contraceptives, Other

- ***Class Overview: Vaginal***

- etonogestrel/ethinyl estradiol ring - (Nuvaring, Eluryng, Enilloring)
- egesterone acetate/ethinyl estradiol ring - (Annovera)
- lactic acid/citric acid/potassium bitartrate gel - (Phexx)

- ***Class Overview: Progestin IUD***

- levonorgestrel IUD - (Liletta; Skyla; Mirena; Kyleena)

- ***Class Overview: Copper IUD***

- copper IUD - (Paragard; Miudella)



Contraceptives, Other

- ***Class Overview: Implants***

- etonogestrel implant - (Nexplanon)

- ***Class Overview: Injectable***

- medroxyprogesterone acetate (contraceptive) suspension – Depo-Provera

- ***Class Overview: Transdermal***

- norelgestromin/ethinyl estradiol weekly patch – (Gwyn Lo; Xulane; Zafemy)
- levonorgestrel/ethinyl estradiol weekly patch – (Twirla)



Contraceptives, Other

- ***Class Overview: Combination Progestins***
 - medroxyprogesterone acetate tablets - (Provera)
 - norethindrone acetate tablets
 - progesterone micronized capsules - (Prometrium)
- ***Class Overview: Emergency Contraceptives***
 - levonorgestrel (Emergency OC) tablets - (Plan B; One-Step OTC; Aftera OTC; My Choice OTC; My Way OTC; New Day OTC; Option 2 OTC)

Contraceptives

- Hormonal oral contraceptives (OCs) are available in various dosage forms for prevention of pregnancy
- Combination oral contraceptives (COCs) contain estrogen and progestin, while progestin-only products contain progestin alone
- Products differ in the specific hormones they contain and how these hormones are dosed throughout the cycle (hormone phases)
- Traditional OCs are administered daily for 21 days followed by a hormone-free week during which menstruation occurs
- Extended cycle products (e.g., 91-day cycle) delay or completely eliminate the break in hormone use

Contraceptives

- Selection of the most appropriate product for a patient may depend on the desired phases of hormones, cycle length, associated product risks, side effect profile, and tolerability
- Hormones vary in their venous thromboembolism (VTE) risk
- Some OCs have additional indications or ingredients
- Non-contraceptive benefits of OCs include reduced risk of ovarian and endometrial cancer, lower incidence of ectopic pregnancy and benign breast disease, increased hemoglobin levels, more regular menstrual cycles, reduced dysmenorrhea and menorrhagia, and improved hirsutism and acne
- The Centers for Disease Control and Prevention (CDC) recommend COCs and progestin-only OCs as effective methods of contraception

Contraceptives

- Details on the appropriate selection of an effective contraceptive method are described in CDC's published Medical Eligibility Criteria
- The CDC also provides guidance to improve family planning services in the U.S., including the use of contraceptives
- The American College of Obstetricians and Gynecologists (ACOG) confirm the Medical Eligibility Criteria and recommend appropriate use of the criteria for women with co-existing medical conditions who need contraception
- ACOG also released an opinion statement in favor of OTC access for OCs without regard to age, stating that women are capable of self-screening and determining their own eligibility for OCs

Contraceptives

- They also state that pelvic, breast, sexually transmitted infections (STIs), and cancer examinations and screenings should not be used as barriers to OCs
- ACOG states that long-acting reversible contraceptives (LARC) are safe and have higher rates of efficacy, continuation, and satisfaction compared with short-acting contraceptives
- COCs (estrogen/progestin) are generally grouped based on the dosage regimen strategy
 - Most are based on a 28-day monthly cycle and are available as monophasic, biphasic, triphasic, and 4-phase products
 - There are also extended-cycle products and a continuous-cycle product available

Contraceptives

- The use of OCs is associated with increased risks of serious conditions, including MI, thromboembolism, stroke, retinal thrombosis, glucose intolerance, hypertension, hepatic tumors, and gallbladder disease
- Risk of serious morbidity or mortality is very small in healthy women, but underlying risk factors can increase that risk
- Various oral, injectable, and intrauterine progestin-only OC products have been found to have no significant elevated risk of VTE, MI, stroke, or hypertension

Contraceptives

Clinical/Product Updates:

- FDA has extended the duration of use for Nexplanon to up to 5 years for prevention of pregnancy in women of reproductive potential
- A new REMS program has been established for Nexplanon for risk of complications due to improper insertion and removal
- Boxed Warning for risk of complications due to improper insertion and removal has been added to Nexplanon PI

Hypoglycemics, DPP4s



Hypoglycemics, DPP4s

Dipeptidyl Peptidase-4 (DPP-4) Enzyme Inhibitors

alogliptin (Nesina®)	Padagis, Takeda	▪ Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
alogliptin/metformin (Kazano®)	Padagis, Takeda	
alogliptin/pioglitazone (Oseni®)	Perrigo/Padagis, Takeda	
linagliptin (Tradjenta®)	Boehringer Ingelheim	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM
linagliptin/empagliflozin (Glyxambi®)	Boehringer Ingelheim	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM ▪ Empagliflozin is indicated to reduce the risk of cardiovascular (CV) death in adults with T2DM and established cardiovascular disease (CVD)
linagliptin/empagliflozin/ metformin ER (Trijardy® XR)		

Hypoglycemics, DPP4s

Dipeptidyl Peptidase-4 (DPP-4) Enzyme Inhibitors

linagliptin/metformin (Jentadueto®)	Boehringer Ingelheim	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both linagliptin and metformin is appropriate
linagliptin/metformin ER (Jentadueto® XR)		
saxagliptin (Onglyza®)	generic, AstraZeneca	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM
saxagliptin/dapagliflozin (Qtern®)	AstraZeneca	
saxagliptin/metformin ER (Kombiglyze® XR)	generic, AstraZeneca	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both saxagliptin and metformin is appropriate
sitagliptin (Januvia®)	Merck Sharp & Dohme	▪ Adjunct to diet and exercise to improve glycemic control in adults with T2DM
sitagliptin (Zituvio™)	Zydus*	
sitagliptin (Brynovin™)	Arbor	

Hypoglycemics, DPP4s



Drug	Manufacturer	Indications
(DPP-4) Enzyme Inhibitors (continued)		
sitagliptin/ertugliflozin (Steglujan®)	Merck Sharp & Dohme	<ul style="list-style-type: none"> Adjunct to diet and exercise to improve glycemic control in adults with T2DM
sitagliptin/metformin (Janumet®)	Merck Sharp & Dohme	<ul style="list-style-type: none"> Adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with sitagliptin and metformin is appropriate
sitagliptin/metformin (Zituvimet)	Zydus	<ul style="list-style-type: none"> Adjunct to diet and exercise to improve glycemic control in adults with T2DM
sitagliptin/metformin ER (Janumet® XR)	Merck Sharp & Dohme	<ul style="list-style-type: none"> Adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both sitagliptin and metformin ER is appropriate
sitagliptin/metformin ER (Zituvimet® XR)	Zydus	



Hypoglycemics, DPP4s

- It is estimated that over 40.1 million people in the U.S. have DM
- Type 2 diabetes (T2DM) accounts for 90 to 95% of all diagnosed cases of DM
- HbA1c improvements for DPP-4s average 0.5% to 1%
- These agents are weight-neutral and have a low hypoglycemia risk when used as monotherapy or in conjunction with metformin
- Single agent DPP-4 inhibitors are administered orally and are dosed once daily

Hypoglycemics, DPP4s

- TECOS study reported that sitagliptin has a neutral effect on CV risk
- In addition, the CARMELINA trial demonstrated non-inferiority of linagliptin (Tradjenta) to placebo in CV outcomes
- A possible slight increased risk of HF with saxagliptin and alogliptin was found in SAVOR-TIMI and EXAMINE trials, respectively
- Along with metformin, guidelines now recommend GLP-1RAs and SGLT2 inhibitors with proven benefit as first-line treatment options, particularly for patients with atherosclerotic cardiovascular disease, CKD, and HF

Hypoglycemics, DPP4s

- DPP-4 inhibitors, insulin, sulfonylureas, thiazolidinediones (TZDs), and/or alpha-glucosidase inhibitors may be added for glycemic control, as needed
- The 2024 American College of Physicians (ACP) recommended *against* the addition of a DPP-4 inhibitor to metformin and lifestyle modifications for patients with inadequate glycemic control
- Diabetes treatment regimens should be individualized based on factors including:
 - Need for weight loss
 - Hypoglycemia risk
 - Co-morbidities
 - Patient preference
 - Drug adverse effects
 - Drug cost

Hypoglycemics, DPP4s

Clinical/Product Updates:

- FDA approved the first generic for Qtern (dapagliflozin/saxagliptin) 10 mg/5 mg oral tablets
- Labeling for all metformin-containing products has been updated with information regarding risk of lactic acidosis in patients with mitochondrial diseases, such as mitochondrial encephalopathy with lactic acidosis and stroke-like episodes (MELAS) syndrome and maternally inherited diabetes and deafness (MIDD)

Intranasal Rhinitis Agents



Intranasal Rhinitis Agents

FDA-Approved Indications

Drug	Manufacturer	Indication(s)
Nasal Corticosteroids		
beclomethasone (Qnasl®) ¹	Teva Specialty	▪ Treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 4 years of age and older
budesonide OTC ²	generic	▪ Temporary relief of hay fever or other upper respiratory allergies, including nasal congestion, runny nose, sneezing, and itchy nose, in adults and children 6 years of age and older
ciclesonide (Omnaris®) ³	Covis	▪ Treatment of nasal symptoms of seasonal allergic rhinitis in adults and children 6 years of age and older ▪ Treatment of nasal symptoms of perennial allergic rhinitis in adults and children 12 years of age and older
ciclesonide (Zetonna®) ⁴	Covis	▪ Treatment of symptoms associated with seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. ▪ Treatment of symptoms associated with perennial allergic rhinitis in adult and pediatric patients 12 years of age and older.
flunisolide ⁵	generic	▪ Treatment of the nasal symptoms of seasonal or perennial rhinitis.
fluticasone furoate OTC (Flonase® Sensimist™) ⁶	GlaxoSmithKline -Haleon	▪ Temporary relief of symptoms of hay fever or other upper respiratory allergies, including nasal congestion, runny nose, sneezing, itchy nose, and itchy, watery eyes in adults and children 2 years of age and older

Intranasal Rhinitis Agents

fluticasone propionate. ⁷	generic	<ul style="list-style-type: none"> Management of nasal symptoms of perennial non-allergic rhinitis in adults and children 4 years of age and older
fluticasone propionate OTC (Flonase Allergy Relief®) ⁸	generic, GlaxoSmithKline-Haleon	<ul style="list-style-type: none"> Temporary relief of symptoms of hay fever or other upper respiratory allergies, including nasal congestion, runny nose, sneezing, itchy nose, and itchy/watery eyes, in adults and children 4 years of age and older
fluticasone propionate (Xhance®) ⁹	OptiNose	<ul style="list-style-type: none"> Treatment of chronic rhinosinusitis with nasal polyps in patients 18 years of age or older Treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age or older
mometasone furoate. ¹⁰	generic	<ul style="list-style-type: none"> Prophylaxis of nasal symptoms of seasonal allergic rhinitis in adults and children 12 years of age and older Treatment of chronic rhinosinusitis with nasal polyps in patients 18 years of age and older
mometasone furoate OTC (Nasonex® 24HR Allergy) ¹¹	Perrigo	<ul style="list-style-type: none"> Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose
mometasone furoate (Sinuva®). ¹²	Intersect ENT	<ul style="list-style-type: none"> Corticosteroid-eluting implant indicated for the treatment of chronic rhinosinusitis with nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery
triamcinolone OTC (Nasacort® Allergy 24HR). ¹³	generic, Chattem	<ul style="list-style-type: none"> Temporary relief of symptoms of hay fever or other upper respiratory allergies, including nasal congestion, runny nose, sneezing, and itchy nose, in adults and children 2 years of age and older

Intranasal Rhinitis Agents

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Intranasal Antihistamines		
azelastine 0.1%. ¹⁴	generic	<ul style="list-style-type: none">▪ Relief of symptoms of seasonal allergic rhinitis in adults and children 5 years of age and older▪ Relief of symptoms of vasomotor rhinitis in patients 12 years of age and older
azelastine 0.15%. ¹⁵	generic	<ul style="list-style-type: none">▪ Relief of symptoms of seasonal allergic rhinitis in adults and children 6 years of age and older▪ Relief of symptoms of perennial allergic rhinitis in adults and children 6 years of age and older
azelastine OTC (Astepro® Allergy, Children Astepro Allergy). ^{16, 17}	generic, Bayer	<ul style="list-style-type: none">▪ Temporary relief of symptoms due to hay fever or other upper respiratory allergies including nasal congestion, runny nose, sneezing, and itchy nose in adults and children 6 years of age and older
olopatadine. ¹⁸	generic	<ul style="list-style-type: none">▪ Relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 6 years of age and older

Intranasal Rhinitis Agents

Antihistamine and Intranasal Corticosteroid Combinations

azelastine/fluticasone propionate (Dymista®)†. ¹⁹	generic, Meda/Mylan	▪ Relief of symptoms of seasonal allergic rhinitis in adult and pediatric patients 6 years of age and older
olopatadine/mometasone (Ryaltris™)†. ²⁰	Hikma Specialty	▪ Treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older

Others

ipratropium nasal spray 0.03%. ²¹	generic	▪ Symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children 6 years of age and older
ipratropium nasal spray 0.06%. ²²	generic	▪ Symptomatic relief of rhinorrhea associated with the common cold or seasonal allergic rhinitis in adults and children 5 years of age and older

Intranasal Rhinitis Agents

- The American Academy of Otolaryngology recommends the use of intranasal corticosteroids and oral antihistamines as key treatments for AR in adults and children over 2 years of age
- Intranasal antihistamines can be offered for patients with seasonal, perennial, or episodic AR, but they are associated with more frequent dosing and adverse effects
- AAAAI states that if a patient is not adequately controlled on an intranasal corticosteroid or has moderate to severe symptoms, addition of an antihistamine may be considered

Intranasal Rhinitis Agents

- According to the AAAAI practice parameter, for intranasally administered treatment, they recommend inhaled antihistamines as first-line for SAR, intermittent AR, and nonallergic rhinitis (NAR)
- Intranasal corticosteroids are the preferred monotherapy for persistent AR (PAR)
- AAAAI suggests combination of an intranasal corticosteroid and intranasal antihistamine for moderate-to-severe cases of SAR, SAR and PAR that is resistant to monotherapy, and resistant NAR
- An alternative option for rhinorrhea that persists while on intranasal corticosteroids is the addition of intranasal ipratropium

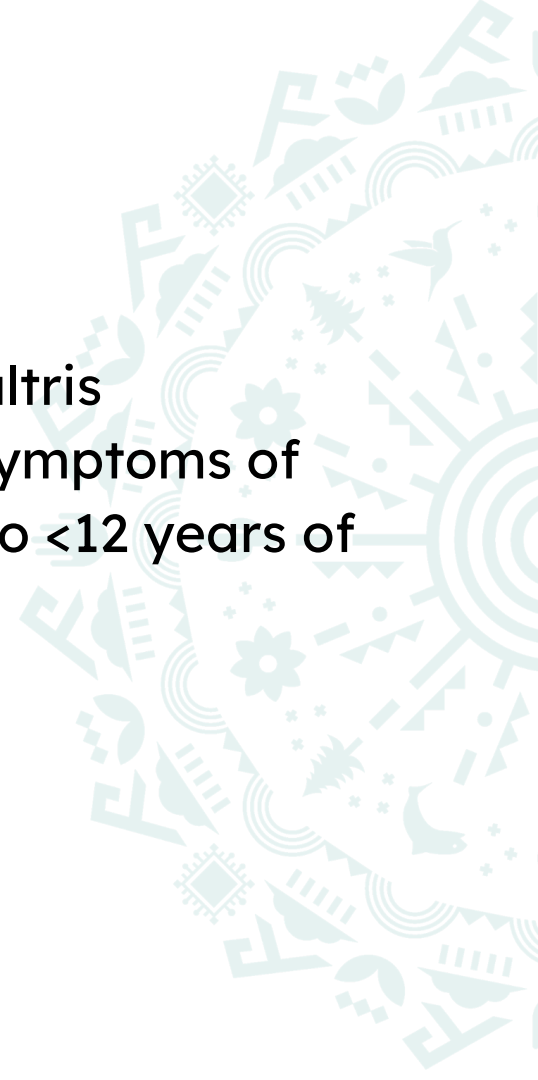
Intranasal Rhinitis Agents

- Intranasal corticosteroids are generally not associated with systemic adverse reactions in adults; local side effects may occur
- Intranasal corticosteroids are similar in efficacy
- Differences among these products include the number of sprays needed per day and dosing frequency
- Intranasal antihistamines offer an alternative to intranasal corticosteroids, oral antihistamines, and intranasal ipratropium for the treatment of AR
- Factors limiting use of intranasal azelastine and olopatadine include route of administration and taste perversion

Intranasal Rhinitis Agents

Clinical/Product Update:

- FDA approved an expanded indication for Ryaltris (olopatadine/mometasone) for treatment of symptoms of seasonal allergic rhinitis to include patients 6 to <12 years of age



Lipotropics, Statins



Lipotropics, Statins

Drug	Manufacturer
amlodipine/atorvastatin (Caduet®) ¹	generic, Pfizer/Viatris
atorvastatin (Atorvaliq®) ²	CMP
atorvastatin (Lipitor®) ³	generic, Pfizer/Viatris
ezetimibe/simvastatin (Vytorin®) ⁴	generic, Organon
fluvastatin ⁵	generic
fluvastatin ER (Lescol XL®) ⁶	generic, Novartis/Sandoz
lovastatin ⁷	generic
lovastatin ER (Altoprev®) ⁸	Covis
pitavastatin calcium (Livalo®) ⁹	generic, Kowa
pitavastatin magnesium (Zypitamag®) ^{*10}	Medicure



Lipotropics, Statins

pravastatin ¹¹	generic
rosuvastatin (Crestor®) ¹²	generic, AstraZeneca
rosuvastatin (Ezallor Sprinkle™)* ¹³	Sun
rosuvastatin/ezetimibe (Roszet®)* ¹⁴	SCOV3†, Althera
simvastatin (Flolipid™)* ¹⁵	Salerno
simvastatin (Zocor®) ¹⁶	generic, Organon

ER = extended release

*Atorvastatin oral suspension (Atorvaliq), ezetimibe/rosuvastatin (Roszet), simvastatin oral suspension (Flolipid), pitavastatin tablet (Zypitamag), and rosuvastatin (Ezallor) were approved as a New Drug Application (NDA) via the 505(b)(2) pathway. A 505(b)(2) NDA is a United States (US) Food and Drug Administration (FDA) approval pathway in which at least some of the information required for approval comes from studies not conducted by or for the applicant.¹⁷ Some of the data used for approval of Atorvaliq, Roszet, Flolipid, Zypitamag, and Ezallor were derived from safety and efficacy data with atorvastatin (Lipitor), rosuvastatin (Crestor) and ezetimibe (Zetia®), simvastatin (Zocor), pitavastatin (Livalo), and rosuvastatin (Crestor), respectively.

† Authorized generic

Lipotropics, Statins

FDA-Approved Indications

Indications	atorvastatin (Atorvaliq, Lipitor), amlodipine/ atorvastatin* (Caduet) ^{18,19,20}	ezetimibe/simvastatin (Vytorin) ²¹	fluvastatin, fluvastatin ER (Lescol XL) ^{22,23}	lovastatin ²⁴	lovastatin ER (Altoprev) ²⁵
Primary hypercholesterolemia ▪ Heterozygous familial and nonfamilial Reduce: Total-C, LDL-C, TG and ApoB Increase: HDL-C	X	X	X	X	X
Heterozygous familial hypercholesterolemia ▪ pediatric	X 10–17 years (Lipitor and Atorvaliq only)	X 10-17 years	X 10–16 years	X 10–17 years	--
Mixed dyslipidemia Fredrickson Type ▪ II _a and II _b Reduce: Total-C, LDL-C, TG and ApoB	X	X	X	X To reduce total-C, LDL-C	X
Increase HDL-C	X	--	--	--	X
Hypertriglyceridemia Fredrickson Type IV	X	--	--	--	--
Primary dysbetalipoproteinemia Fredrickson Type III	X	--	--	--	--
Homozygous familial hypercholesterolemia	X	X	--	--	--

ApoB = apoprotein B; ER = extended release; HDL-C = high density lipoprotein cholesterol; LDL-C = low density lipoprotein cholesterol; TG = triglycerides; Total-C = Total cholesterol

* Caduet is indicated when amlodipine and atorvastatin are both appropriate. Indications for amlodipine are hypertension, chronic stable angina, vasospastic angina, and angiographically documented coronary artery disease (CAD).

Lipotropics, Statins

FDA-Approved Indications (continued)

Indications	atorvastatin (Atorvaliq, Lipitor), amlodipine/atorvastatin* (Caduet)	ezetimibe/simvastatin (Vytorin)	fluvastatin, fluvastatin ER (Lescol XL)	lovastatin	lovastatin ER (Altoprev)
Atherosclerosis slow progression	--	--	X	X	X
CVD <ul style="list-style-type: none"> primary prevention of coronary events 	Reduces risk of MI, stroke, revascularization, angina	--	--	Reduces risk of MI, unstable angina, and need for coronary revascularization	Reduces risk of MI, unstable angina, coronary revascularization
CHD <ul style="list-style-type: none"> secondary prevention of coronary events 	Reduces risk of MI, stroke in patients with T2DM without CHD; Reduces risk of MI, stroke, CHF hospitalization, angina, and revascularization in CHD patients	--	Reduces risk of coronary revascularization	--	--

CVD = cardiovascular disease; CHD = coronary heart disease; CHF = congestive heart failure; ER = extended release; MI = myocardial infarction; T2DM = type 2 diabetes mellitus

* Caduet is indicated when amlodipine and atorvastatin are both appropriate. Indications for amlodipine are hypertension, chronic stable angina, vasospastic angina, and angiographically documented coronary artery disease (CAD).

Lipotropics, Statins

FDA-Approved Indications (continued)

Indications	pitavastatin (Livalo, Zypitamag) ²⁶	pravastatin ²⁷	rosuvastatin (Crestor, Ezallor Sprinkle) ^{28,29}	rosuvastatin/ ezetimibe (Roszet) ³⁰	simvastatin (Flolipid, Zocor) ^{31,32}
Primary hypercholesterolemia ▪ Heterozygous familial and nonfamilial Reduce: Total-C, LDL-C, TG and ApoB	X	X	X	X†	X
Heterozygous familial hypercholesterolemia ▪ pediatric	X 8 years and <u>older</u> (Livalo only)	X 8 years and older	X 8–17 years	--	X 10–17 years
Mixed dyslipidemia Fredrickson Type ▪ II _a and II _b Reduce: Total-C, LDL-C, TG and ApoB	--	X	X†	--	X
Increase HDL-C	X§	X	X†	--	X
Hypertriglyceridemia - Fredrickson Type IV	--	X	X	--	X
Primary dysbetalipoproteinemia - Fredrickson Type III	--	X	X	--	X
Homozygous familial hypercholesterolemia	--	--	X 7–17 years	X	X
Atherosclerosis ▪ slow progression	--	X	X	--	--

ApoB = apoprotein B; HDL-C = high density lipoprotein cholesterol; LDL-C = low density lipoprotein cholesterol; TG = triglycerides; Total-C = Total cholesterol

† Rosuvastatin/ezetimibe is approved as an adjunct to diet in patients with primary *non-familial* hyperlipidemia to reduce LDL-C

‡ Approval for rosuvastatin (Crestor) only

§ Livalo only

Lipotropics, Statins

FDA-Approved Indications (continued)

Indications	pitavastatin (Livalo, Zypitamag) ³³	pravastatin ³⁴	rosuvastatin (Crestor, Ezallor Sprinkle) ^{35,36}	rosuvastatin/ ezetimibe (Roszet) ³⁷	simvastatin (Flolipid, Zocor) ^{38,39}
CVD ■ primary prevention of coronary events	--	Reduces risk of MI, myocardial revascularization, CV mortality	Reduces risk of major adverse CV events (CV death, nonfatal MI, nonfatal stroke, revascularization) in patients without clinically evident CHD, but with multiple risk factors [¶]	--	--
CHD ■ secondary prevention of coronary events	--	Reduces risk of MI, myocardial revascularization, CV mortality, stroke/TIA	--	--	Reduces total mortality risk by reducing CHD death, MI, stroke, and need for revascularization

CV = cardiovascular; CVD = cardiovascular disease; CHD = coronary heart disease; MI = myocardial infarction; TIA = transient ischemic attack

¶ Ezallor Sprinkle is similarly indicated to reduce the risk of stroke, MI, and revascularization in patients without clinically evident CHD but with multiple risk factors

Lipotropics, Statins

- Cardiovascular disease (CVD) remains the leading cause of mortality in the US; it accounted for more than 900,000 deaths in 2023
- According to the American Heart Association (AHA), nearly half of US adults had some form of CVD between 2021 and 2023
- The direct and indirect costs associated with CVD exceeded \$400 billion in 2021 to 2022
- The 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase inhibitors, also known as statins, are the standard treatment in lowering cholesterol levels

Lipotropics, Statins

- All statins lower LDL-C, although to differing degrees, in a dose-related manner
- They have demonstrated clear improvements in primary and secondary prevention of CV events
- Statins have shown a decrease in the incidence of MI, stroke, need for revascularization, angina hospitalization, CV mortality, and overall mortality

Lipotropics, Statins

- The 2026 ACC/AHA Dyslipidemia Guideline recommends statins as first-line lipid-lowering therapy in nearly all patients
- Their updated risk assessment framework supports consideration of lipid-lowering therapy at lower estimated risk thresholds than their previous guidelines
- The guideline also reintroduced LDL-C and non-high-density lipoprotein cholesterol (HDL-C) treatment goals
- Patients 30 to 79 years old at low 10-y estimated risk for ASCVD but with an LDL-C of 160 to 189 mg/dL (4.1-4.9 mmol/L) or a 30-y ASCVD risk $\geq 10\%$ for those aged 30-59 years are recommended to initiate moderate-intensity statin therapy

Lipotropics, Statins

- Adults at intermediate 10-y estimated risk for ASCVD may need a moderate- or high-intensity statin
- High-intensity statin therapy is expected to reduce LDL-C by at least 50%, moderate-intensity statin therapy typically reduces LDL-C by 30% to 49%, and low-intensity statin therapy by less than 30%

Lipotropics, Statins

- AACE and the American College of Endocrinology (ACE) recommend aggressive lipid-modifying therapy to lower LDL-C, with statins as the drugs of choice
- They provide different LDL-C and triglyceride (TG) goals based on the individual's risk for CV events
- Target non-HDL-C and apolipoprotein B (apo B) levels are also provided
- Their algorithm recommends treatment intensification with the addition of other LDL-C lowering agents as needed to reach treatment goals

Lipotropics, Statins

- US Preventive Services Task Force (USPSTF) recommends a statin for the *primary* prevention of CVD in adults ages 40 to 75 years with ≥ 1 CVD risk factor and an estimated 10-year calculated CVD event risk of $\geq 10\%$
- USPSTF states that clinicians may selectively prescribe statin therapy in adults ages 40 to 75 years with ≥ 1 CVD risk factor and an estimated 10-year calculated CVD event risk of 7.5% to $< 10\%$
- There is insufficient evidence to adequately assess the risk versus benefits of initiating a statin in adults ≥ 76 years of age for primary prevention of CVD events and mortality

Lipotropics, Statins

- The National Lipid Association (NLA) recommends lipid levels be used in conjunction with other ASCVD risk factors to assess overall risk
- Moderate to high-intensity statin therapy is considered first-line for patients at high or very high-risk for an ASCVD event
- The AHA advised that treatment for familial hypercholesterolemia (FH) should be based on LDL-C levels
- Initial drug monotherapy for those with FH includes high-intensity statin therapy

Lipotropics, Statins

- The AHA/American Stroke Association (ASA) guideline recommends that patients with ischemic stroke in the absence of CHD, no sources of cardiac embolism, and with LDL-C > 100 mg/dL be prescribed atorvastatin 80 mg daily
- The addition of ezetimibe to a statin is recommended for patients with ischemic stroke or transient ischemic attack (TIA) who have not reached the goal of <70 mg/dL for LDL-C
- They also recommend the addition of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor for very high-risk patients who have not reached the goal of < 70 mg/dL for LDL-C despite treatment with a statin and ezetimibe

Lipotropics, Statins

- KDIGO updated recommendations for the evaluation, management and treatment of CKD in children and adults who are not receiving kidney replacement therapy
- Statins are recommended for adults with CKD who are ≥ 50 years of age and in patients with CKD aged 18-49 years with known CAD, DM, prior ischemic stroke or estimated 10-year incidence of coronary death or nonfatal MI $> 10\%$

Lipotropics, Statins

Clinical/Product Updates:

- Brand-name Lescol XL (fluvastatin ER) and the authorized generics are being discontinued; other generics remain available
- FDA approved a broader cardiovascular risk reduction indication for rosuvastatin with removal of restriction around high-sensitivity C-reactive protein levels
- HoFH indication was updated with clarification of lifestyle language

Ophthalmics, Glaucoma Agents



Ophthalmics, Glaucoma Agents

Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
Prostaglandin Analogue		
bimatoprost (Lumigan®) <i>generic, Allergan/AbbVie</i>	Reduction of intraocular pressure (IOP) in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 7 to 8 mmHg
Bimatoprost (Zolymbus™) <i>Thea Pharma</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> Non-inferior to bimatoprost 0.01% ophthalmic solution
Latanoprost (Xalatan®) <i>generic, Viartis</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 6 to 8 mmHg
Latanoprost (Iyuzeh) <i>Thea Pharma</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 3 to 8 mmHg
latanoprostene bunod (Vyzulta®) <i>Bausch & Lomb</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> Up to 7 to 9 mmHg
tafluprost (Zioptan®) <i>generic, Thea Pharma</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 5 to 8 mmHg
travoprost (Travatan® Z) <i>generic, Sandoz</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 7 to 8 mmHg
omidenedapag isopropyl (Omlonti®) <i>Ocuvex</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> Open-angle glaucoma Ocular hypertension 	<ul style="list-style-type: none"> 5 to 7 mmHg

Ophthalmics, Glaucoma Agents

Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
Beta Blockers		
carteolol <i>generic</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	Reduced mean IOP by 22% to 25%
levobunolol <i>generic</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	7 to 8 mmHg
timolol (Betimol®) <i>generic, Thea Pharma</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	Efficacy and safety profile was similar to that of timolol maleate
timolol maleate (Timoptic in Ocudose®) <i>generic, Bausch & Lomb</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	20-25%
timolol maleate long-acting <i>generic</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	Efficacy is equally effective as timolol maleate ophthalmic solution administered twice daily
timolol maleate long-acting (Istalol®) <i>generic, Bausch & Lomb</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	6 to 7 mmHg
betaxolol (Betoptic S®) <i>generic, Novartis</i>	Lowering IOP in patients with: <ul style="list-style-type: none"> Chronic open-angle glaucoma Ocular hypertension 	Betaxolol 0.5% reduced mean IOP 25% from baseline; betaxolol 0.25% and 0.5% are clinically equivalent

Ophthalmics, Glaucoma Agents

Alpha-2-Adrenergic Agonists

Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
apraclonidine <i>generic</i>	Short-term adjunctive therapy, in patients on maximally tolerated medical therapy, who require additional IOP reduction; patients taking apraclonidine to delay surgery, should have frequent follow-up examinations and treatment should be discontinued if the IOP rises significantly	20%–25%
apraclonidine (Iopidine®) <i>Harrow Eye</i>	To control or prevent post-surgical elevations in IOP that occur in patients after argon laser trabeculoplasty, argon laser iridotomy or Nd:YAG posterior capsulotomy	20%–25%
brimonidine (Alphagan P®) <i>generic, Allergan/AbbVie</i>	Lowering IOP in patients with: <ul style="list-style-type: none">• Chronic open-angle glaucoma• Ocular hypertension	2 to 6 mmHg

Ophthalmics, Glaucoma Agents

Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
Carbonic Anhydrase Inhibitors		
brinzolamide (Azopt®) <i>generic, Sandoz</i>	Lowering IOP in patients with: <ul style="list-style-type: none">• Open-angle glaucoma• Ocular hypertension	4 to 5 mmHg
dorzolamide <i>generic</i>	Lowering IOP in patients with: <ul style="list-style-type: none">• Open-angle glaucoma• Ocular hypertension	3 to 5 mmHg
Rho Kinase Inhibitors		
netarsudil (Rhopressa®) <i>Alcon</i>	Lowering IOP in patients with: <ul style="list-style-type: none">• Open-angle glaucoma• Ocular hypertension	Up to 5 mmHg

Ophthalmics, Glaucoma Agents

Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
Cholinergic Agonist		
pilocarpine <i>generic</i>	<ul style="list-style-type: none">• Lowering IOP in patients with:<ul style="list-style-type: none">○ Open-angle glaucoma○ Ocular hypertension• Management of acute angle-closure glaucoma• Prevention of postoperative elevated IOP associated with laser surgery• Induction of miosis	3 to 7 mmHg
Cholinesterase Inhibitor		
echothiophate iodide (Phospholine Iodide®) <i>Fera</i>	<ul style="list-style-type: none">• Reduction of elevated IOP• Accommodative esotropia	20-25%

Ophthalmics, Glaucoma Agents



Drug <i>Manufacturer</i>	Indications	IOP-lowering Effect
Combination Agents		
netarsudil/latanoprost (Rocklatan®) <i>Alcon</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> • Open-angle glaucoma • Ocular hypertension` 	Combination agent provided an additional 1 to 3 mmHg reduction in IOP over either agent alone
brimonidine/brinzolamide (Simbrinza®) <i>Alcon</i>	Reduction of IOP in patients with: <ul style="list-style-type: none"> • Open-angle glaucoma • Ocular hypertension <p>For patients who require adjunctive or replacement therapy due to inadequately controlled IOP</p>	Combination agent provided an additional 1 to 3 mmHg reduction in IOP over either agent alone
brimonidine/timolol (Combigan®) generic, Allergan	Reduction of IOP in patients with: <ul style="list-style-type: none"> • Open-angle glaucoma • Ocular hypertension 	Combination agent provided an additional 1 to 3 mmHg reduction in IOP over either agent alone
dorzolamide/timolol (Cosopt®, Cosopt PF®) generic, Thea	Reduction of IOP in patients with: <ul style="list-style-type: none"> • Open-angle glaucoma • Ocular hypertension <p>For patients who did not achieve target IOP with beta blockers.</p>	Combination agent provided an additional 1 to 3 mmHg reduction in IOP over either agent alone

Ophthalmics, Glaucoma Agents

- Over 3 million people in the U.S. suffer from glaucoma
- It is the second most common cause of permanent blindness in the U.S., and is the leading cause of blindness among Hispanics
- Open-angle glaucoma is associated with reduced flow through the trabecular meshwork and accounts for the majority of cases
- In closed-angle glaucoma, the iris is pushed forward against the trabecular meshwork, blocking fluid from escaping
- The goal of treatment is to maintain the IOP in a range at which the optic nerve head and retinal nerve fiber layer are stable

Ophthalmics, Glaucoma Agents

- If an agent does not adequately decrease IOP, the patient can be switched to another therapy, or an additional medication can be added
- Fixed-dose combinations may potentially increase adherence and decrease exposure to preservatives
- The American Academy of Ophthalmology (AAO) guidelines state that prostaglandin analogs are the most effective drugs at lowering IOP and can be considered as initial medical therapy
- In clinical trials, prostaglandin agonists were at least as effective as agents from other classes, and frequently showed superior efficacy compared to timolol (Timoptic)

Ophthalmics, Glaucoma Agents

- Prostaglandin analogs have also been shown to have an additive effect when used with beta blocker therapy
- Direct-acting miotics are second- or third-line therapy due to frequent administration and lower tolerability

Ophthalmics, Glaucoma Agents

Clinical/Product Updates:

- FDA has approved aceclidine (Vizz) indicated for the treatment of presbyopia in adults
- FDA has approved Yuvezzi for the treatment of presbyopia in adults
- FDA reported that manufacture of Vuity 1.25% ophthalmic solution will be discontinued; generics remain

Phosphate Binders



Phosphate Binders

FDA-Approved Indications

Drug	Manufacturer	Indication(s)
calcium acetate tablet* ¹	generic	To reduce serum phosphorus in adults with end stage renal disease (ESRD)
calcium acetate capsule† ²	generic	For the reduction of serum phosphorus in adults with ESRD
ferric citrate (Auryxia®) ³	Keryx Biopharmaceuticals	For the control of serum phosphorus levels in adults with chronic kidney disease (CKD) on dialysis Treatment of iron deficiency anemia in adults with CKD not on dialysis
lanthanum carbonate (Fosrenol®) ⁴	generic, Shire	To reduce serum phosphate in adults with ESRD
sevelamer carbonate (Renvela®) ⁵	generic, Genzyme	Control of serum phosphorus in patients ≥ 6 years of age with CKD on dialysis
sevelamer hydrochloride‡ ⁶	generic	For the control of serum phosphorus in adults with CKD on dialysis
sucroferric oxyhydroxide (Velphoro®) ⁷	Fresenius Medical Care	For the control of serum phosphorus in patients ≥ 9 years of age with CKD on dialysis
tenapanor hydrochloride (Xphozah®) ⁸	Ardelyx	To reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy

* Generic for PhosLo® tablets by Fresenius Medical Care. Previously, another equivalent generic product was available under the trade name Eliphos® by Hawthorn. Both the PhosLo tablet and Eliphos products have been discontinued.

† Generic for PhosLo® gelcaps/capsules by Fresenius Medical Care; the brand has been discontinued.

‡ Generic for Renagel tablets by Genzyme; the brand has been discontinued.

Phosphate Binders

- CKD affects approximately 37 million Americans in the U.S.
- As kidney function deteriorates, the ability to eliminate phosphorus declines, resulting in hyperphosphatemia, one of the complications of CKD
- Elevated levels of phosphorus inhibit the conversion of 24-hydroxyvitamin D to 1,25-dihydroxyvitamin D (calcitriol)
- The reduction in calcitriol decreases intestinal absorption of calcium and eventually leads to hypocalcemia

Phosphate Binders

- In end stage renal disease (ESRD), patients are at risk for several complications of hyperphosphatemia, including the development of renal bone disease and extraosseous calcifications of soft tissue and vasculature
- Hyperphosphatemia (> 6.5 mg/dL) is associated with increased risk of death
- All phosphate binders are considered effective in reducing serum phosphate levels
- Treatment guidelines do not strongly prefer one agent in this class over another for adults

Phosphate Binders

- The National Kidney Foundation (NKF) 2025 Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) under the KDIGO advise that treatment of hyperphosphatemia include the reduction of dietary phosphorus, phosphate binding therapy, and removal of phosphorus by dialysis
- Although the recommendation is not graded, they advise basing decisions regarding phosphate-lowering treatment on progressively or persistently elevated serum phosphate rather than to prevent hyperphosphatemia

Phosphate Binders

Clinical/Product Update:

- FDA approved the first generic for Auryxia oral tablet





Supplemental Rebate Drug Class Review

Hind Douiki, Pharm.D.

HIV/AIDS



HIV/AIDS



Drug	Manufacturer	Indication(s)
Attachment Inhibitor		
fostemsavir (Rukobia), FTR	ViiV	Treatment of human immunodeficiency virus type 1 (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
Capsid Inhibitor		
lenacapavir (Sunlenca®), LEN	Gilead	Treatment of HIV-1 infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
lenacapavir (Yeztugo®), LEN	Gilead	Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition; individuals must have a negative HIV-1 test prior to initiating YEZTUGO
C-C Chemokine Receptor 5 (CCR5) Antagonist		
maraviroc (Selzentry®), MVC	generic, ViiV	Combination antiretroviral treatment of adults and pediatric patients weighing ≥ 2 kg infected with only CCR5-tropic HIV-1

HIV/AIDS

Fusion Inhibitor

enfuvirtide (Fuzeon®), T20 or ENF	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
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Integrase Strand Transfer Inhibitors (INSTIs)

cabotegravir (Vocabria), CBV	ViiV	<ul style="list-style-type: none">▪ In combination with rilpivirine for short-term treatment of HIV-1 infection in adults and adolescents ≥ 12 years of age and weighing ≥ 35 kg who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine▪ For use as either oral lead-in to assess the tolerability of cabotegravir prior to administration of cabotegravir/rilpivirine extended-release (ER) injectable suspensions or cabotegravir ER injectable suspension; or oral therapy for patients who will miss planned injection dosing with cabotegravir/rilpivirine▪ For at-risk adults and adolescents weighing ≥ 35kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating for HIV-1 PrEP
cabotegravir ER (Apretude), CBV	ViiV	In at-risk adults and adolescents weighing ≥ 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating cabotegravir ER (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP

HIV/AIDS

Integrase Strand Transfer Inhibitors (INSTIs) (continued)

dolutegravir (Tivicay [®] , Tivicay PD [®]), DTG	ViiV	<ul style="list-style-type: none">▪ 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 adults 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 component
raltegravir (Isentress [®] , Isentress HD [®]), RA	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	Merck	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg 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, EFV	generic	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

HIV/AIDS



etravirine (Intelence®), ETR	generic, Janssen	In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients ≥ 2 years old
nevirapine, NVP	generic	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and in pediatric patients ≥ 15 days old
nevirapine ER, NVP	generic	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and in children ≥ 6 years of age with a body surface area (BSA) $\geq 1.17 \text{ m}^2$
rilpivirine (Edurant®, Edurant® PED), RPV	Janssen	<ul style="list-style-type: none"> In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients ≥ 2 years of age and weighing $\geq 14 \text{ kg}$ with HIV-1 RNA $\leq 100,000$ copies/mL In combination with cabotegravir (Vocabria) for short-term treatment of HIV-1 infection in adults and adolescents ≥ 12 years of age and weighing $\geq 35 \text{ kg}$ 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 for use as: (1) oral lead-in to assess the tolerability of rilpivirine prior to administration of rilpivirine ER injectable suspension, a component of Cabenuva, or (2) oral therapy for patients who will miss planned injection dosing with Cabenuva

HIV/AIDS

Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

abacavir (Ziagen®), ABC	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection
emtricitabine (Emtriva®), FTC	generic, Gilead	In combination with other antiretroviral agents for the treatment of HIV-1 infection
lamivudine (Epivir®), 3TC	generic, ViiV	<p>In combination with other antiretroviral agents for the treatment of HIV-1 infection</p> <p>Limitation of Use: The dosage of this product is for HIV and not for hepatitis B virus (HBV)</p>
zidovudine (Retrovir®), AZT	generic, ViiV	<ul style="list-style-type: none">▪ In combination with other antiretroviral agents for the treatment of HIV-1 infection▪ Prevention of maternal-fetal HIV-1 transmission
tenofovir disoproxil fumarate (Viread®), TDF	generic, Gilead	<ul style="list-style-type: none">▪ 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

HIV/AIDS



Pharmacokinetic Enhancer

cobicistat (Tybost®), COBI or c	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 ≥ 14 kg co-administered with atazanavir or weighing ≥ 15 kg co-administered with darunavir
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Protease Inhibitors (PIs)

atazanavir (Reyataz®), ATV	generic, Bristol-Myers Squibb	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adult and pediatric patients ≥ 3 months and weigh ≥ 5 kg
darunavir (Prezista®), DRV	generic, Janssen	<ul style="list-style-type: none">Treatment of HIV-1 infection in adult patients, including pregnant womenTreatment of HIV-1 infection in pediatric patients ≥ 3 years of age who weigh ≥ 10 kg <p>Limitation of use: Prezista must be co-administered with ritonavir and with other antiretroviral agents</p>
fosamprenavir (Lexiva®), FPV	generic, ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection

HIV/AIDS

Protease Inhibitors (PIs) (continued)

nelfinavir (Viracept®), NFV	ViiV	In combination with other antiretroviral agents for the treatment of HIV-1 infection
ritonavir (Norvir®), RTV or r	generic, Abbvie	In combination with other antiretroviral agents for the treatment of HIV-1 infection
tipranavir (Aptivus®), TPV	Boehringer Ingelheim	Co-administered with ritonavir for combination antiretroviral treatment of HIV-1 infected patients ≥ 36 kg who are treatment-experienced and infected with HIV-1 strains resistant to > 1 PI; not indicated for use in treatment-naïve patients

Recombinant Monoclonal Antibody

ibalizumab-uiyk (Trogarzo®)	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
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HIV/AIDS

Combination Products – Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTIs)

abacavir/lamivudine (Epzicom®), ABC/3TC	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
emtricitabine/tenofovir alafenamide (Descovy®), FTC/TAF	Gilead	<p>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 other antiviral agents (including darunavir and cobicistat, but not other PIs that require CYP3A inhibitors); for HIV-1 in pediatric patients weighing ≥ 14 kg to < 35 kg</p> <p>Indicated in at-risk adults and adolescents weighing ≥ 35 kg for 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</p>
emtricitabine/tenofovir disoproxil fumarate (Truvada®), FTC/TDF	generic, Gilead	<p>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;</p> <p>Indicated in at-risk adults and adolescents weighing ≥ 35 kg for 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</p>
lamivudine/tenofovir disoproxil fumarate (Cimduo®), 3TC/TDF	Mylan-Viatris	A combination of 2 NRTIs indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg
lamivudine/zidovudine (Combivir®), 3TC/AZT	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

HIV/AIDS

Combination Products – Protease Inhibitors (PIs) or PIs + Pharmacokinetic Enhancer

atazanavir/cobicistat (Evotaz®), ATV/c	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	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 ≥ 25 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)
lopinavir/ritonavir (Kaletra®), LPV/r	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)

HIV/AIDS

Combination Products – Multiple Classes

bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy®), BIC/FTC/TAF	Gilead	As a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 14 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 with no history of treatment failure and no known substitutions associated with resistance to bictegravir or tenofovir; or have been treated with antiretroviral treatment and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir
cabotegravir/rilpivirine, ER injection (Cabenuva), CAB/RPV	ViiV	A co-packaged product containing an INSTI and NNRTI indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents ≥ 12 years of age and weighing ≥ 35 kg 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 with no known or suspected resistance to either cabotegravir or rilpivirine
darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®), DRV/c/FTC/TAF	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

HIV/AIDS



Combination Products – Multiple Classes (*continued*)

dolutegravir/abacavir/lamivudine (Triumeq, Triumeq PD), DTG/ABC/3TC	ViiV	A co-formulated product containing 1 INSTI and 2 NRTIs indicated for the treatment of HIV-1 infection in adults and pediatric patients ≥ 3 months of age and weighing ≥ 6 kg
dolutegravir/lamivudine (Dovato®), DTG/3TC	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 and adolescents 12 years of age and older and weighing ≥ 25 kg 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	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

HIV/AIDS



Combination Products – Multiple Classes (continued)

doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®), DOR/3TC/TDF	Merck	A co-formulated product containing 1 NNRTI and 2 NRTIs indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥ 35 kg 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	generic, Gilead	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	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
efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi Lo®), EFV/3TC/TDF	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 adults and pediatric patients weighing ≥ 35 kg

HIV/AIDS

Combination Products – Multiple Classes (continued)

elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (TAF) (Genvoya®), EVG/c/FTC/TAF	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	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	Gilead	A combination product containing 2 NRTIs and 1 NNRTI indicated for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 25 kg as initial therapy in treatment-naïve patients with HIV-1 RNA $\leq 100,000$ 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	Mylan , 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 $\leq 100,000$ 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

HIV/AIDS

- Per the Joint United Nations Programme on HIV/AIDS (UNAIDS), in partnership with the World Health Organization (WHO), goals include the 95-95-95 treatment target
- 95% of people living with HIV are aware of their status, 95% of these patients are receiving treatment, and 95% have achieved viral suppression
- At the end of 2024, the number of new HIV infections and AIDS-related deaths decreased by 40% and 56%, respectively, since 2010
- Initial regimen selection should be guided by patient characteristics, including comorbidities, drug-drug interaction possibilities, toxicity risk, regimen complexity, and virologic efficacy

HIV/AIDS

- The 2025 Department of Health and Human Services (DHHS) HIV Treatment Guidelines strongly support universal, early initiation of antiretroviral therapy (ART) for all people with HIV
- This recommendation is supported by the START and TEMPRANO studies, which showed that early ART initiation reduced serious illness and death by approximately 50%
- The guidelines emphasize that achieving and maintaining viral suppression improves health outcomes and effectively prevents sexual transmission when HIV RNA remains below 200 copies/mL

HIV/AIDS

- The International Antiviral Society (IAS-USA) recommends that all individuals diagnosed with HIV begin ART within 7 days of diagnosis
- Most patients can start treatment with either a 2-drug or 3-drug regimen containing an integrase strand transfer inhibitor (INSTI)
- Abacavir is no longer recommended as part of most initial ART regimen
- The guidelines also provide specific recommendations for pregnant individuals, patients with opportunistic infections, tuberculosis coinfection, Cancer, and individuals starting ART after PrEP failure
- They consider targeted HIV drug resistance testing critical for optimizing therapy

HIV/AIDS

- All guidelines advise initiating ART regardless of cluster of differentiation (CD)4 cell counts in HIV-infected individuals
- Viral suppression requires multidrug therapy involving 2 or more antiretroviral subclasses
- Current HIV regimens typically include drugs from one or more of these classes:
 - Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTIs)
 - Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)
 - Protease Inhibitors (PIs)
 - Integrase Strand Transfer Inhibitors (INSTIs)
- NNRTIs are effective but have a low barrier to resistance and significant cross-resistance within the class

HIV/AIDS

- PIs are Highly potent with strong durability and higher resistance barriers, but are associated with more adverse effects, drug interactions, and often require pharmacologic boosting with ritonavir or cobicistat
- INSTIs are currently preferred as first-line therapy because they have favorable safety profiles and high barriers to resistance
- C-C chemokine receptor 5 (CCR5) antagonists are effective in selected patients but require specialized tropism testing and are generally considered alternative options
- For heavily treatment-experienced patients with multidrug-resistant HIV, newer agents are available including lenacapavir (Sunlenca), ibalizumab-uiyk (Trogarzo), and fostemsavir (Rukobia)

HIV/AIDS

- Several FDA-approved medications are available for pre-exposure prophylaxis (PrEP)
- Individuals must be confirmed HIV-negative before starting and while receiving PrEP
- In pediatric patients with HIV, early treatment is emphasized, starting hours after time of birth

HIV/AIDS

Clinical/Product Updates:

- Enfuvirtide (Fuzeon) was discontinued
- Brand Epzicom (abacavir/lamivudine) tablet was discontinued; generics are available
- Selzentry 20 mg/mL oral solution has been discontinued. Selzentry tablets and generic miraviroc tablets remain available
- FDA approved Prezcobix PED (darunavir/cobicistat) tablets for oral suspension for the treatment of HIV-1 infection in pediatric patients aged ≥ 3 years old and weighing ≥ 15 kg
- FDA approved the first generic for Edurant (rilpivirine) oral tablet

HIV/AIDS

- Brand Intelence 100 mg strength and the associated authorized generic has been discontinued
- Emtriva 200 mg capsules have been discontinued. Generics remain
- Norvir 100 mg oral powder has been discontinued
- Kaletra 20 mg/mL & 80 mg/mL oral solution were discontinued
- FDA has approved fixed-dose combo product Brixleno, which contains bictegravir and lenacapavir, as a complete regimen for 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 stable ART with no known or suspected resistance to the individual components of Brixleno

HIV/AIDS

- Sunlenca tablets have been approved for oral loading as a component of the initiation regimen with bictegravir and lenacapavir (Bixlenvo) fixed-dose combo tablets, for the treatment of HIV-1 in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable antiretroviral regimen with no known or suspected resistance to the individual components
- FDA has approved Tivicay PD tablets for oral suspension to treat HIV-1 infection in newborns (treatment-naïve or -experienced but INSTI-naïve) weighing ≥ 2 kg, in combo with other antiretroviral agents

Lipotropics, Other



Lipotropics, Other

Drug	Manufacturer	Indication(s)
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor		
bempedoic acid (Nexletol®) ¹	Esperion	<ul style="list-style-type: none"> As adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) Reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking statin)
ACL Inhibitor/Cholesterol Absorption Inhibitor		
bempedoic acid/ezetimibe (Nexlizet®) ²	Esperion	<ul style="list-style-type: none"> As adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) Reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking statin)

Lipotropics, Other

Angiopoietin-like 3 (ANGPTL3) Inhibitor		
evinacumab-dgnb (Evkeeza®) ³	Regeneron	<ul style="list-style-type: none"> As an adjunct to diet and exercise and other LDL-C lowering therapies to reduce LDL-C in adult and pediatric patients ≥ 1 year old with homozygous familial hypercholesterolemia (HoFH)
Apolipoprotein B Synthesis Inhibitor		
lomitapide* (Juxtapid®) ⁴	Chiesi	<ul style="list-style-type: none"> Reduction of LDL-C, total cholesterol (TC), apolipoprotein B (Apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with HoFH, as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available
Apolipoprotein C-III (APOC3)–Directed Antisense Oligonucleotide (ASO)		
olezarsen (Tryngolza®) ⁵	Ionis	<ul style="list-style-type: none"> As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)
APOC3–Directed Small Interfering Ribonucleic Acid (siRNA)		
plozasiran (Redemplo®) ⁶	Arrowhead	<ul style="list-style-type: none"> As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)

* Limitations of use for lomitapide* (Juxtapid®) include that (1) safety and effectiveness have not been established in patients with hypercholesterolemia who do not have HoFH, including those with HeFH; and (2) the effects on CV morbidity and mortality have not been determined.

Lipotropics, Other

Bile Acid Sequestrants		
cholestyramine (Questran®, Questran® Light) ⁵	generic, Par	<ul style="list-style-type: none"> Primary hypercholesterolemia Relief of pruritus associated with partial biliary obstruction
colesevelam† (Welchol®) ⁶	generic, Cosette	<ul style="list-style-type: none"> As adjunct to diet and exercise to reduce elevated LDL-C in adults with primary hyperlipidemia Reduction of LDL-C levels in boys and postmenarchal girls 10 to 17 years of age with HeFH who are unable to reach LDL-C target despite adequate trial of dietary therapy and lifestyle modifications Glycemic control in adults with type 2 diabetes mellitus (T2DM)
colestipol (Colestid®) ^{7,8}	generic, Pharmacia- Upjohn	<ul style="list-style-type: none"> Primary hypercholesterolemia

* Limitations of use for evinacumab-dgnb (Evkeeza) include that (1) safety and effectiveness have not been established in patients with other causes of hypercholesterolemia, including those with HeFH; and (2) the effects on CV morbidity and mortality have not been determined.

† Limitations of use for colesevelam (Welchol) include that (1) it should not be used to treat type 1 diabetes mellitus or diabetic ketoacidosis; (2) its effects on CV morbidity and mortality have not been established; (3) it has not been studied in T2DM in combination with a dipeptidyl peptidase 4 (DPP4) inhibitor; (4) it has not been studied in Frederickson Type I, III, IV, and V dyslipidemias; and (5) it has not been studied in children < 10 years of age or in premenarchal girls.

Lipotropics, Other

FDA-Approved Indications (continued)

Drug	Manufacturer	Indication(s)
Cholesterol Absorption Inhibitors		
ezetimibe (Zetia®) ⁹	generic, Organon	<ul style="list-style-type: none"> As adjunct to diet to reduce elevated LDL-C in adults with primary hyperlipidemia, including HeFH (in combination with a statin, or as monotherapy when additional LDL-C lowering therapy is not possible) As adjunct to diet to reduce elevated LDL-C in patients ≥ 10 years of age with HeFH (in combination with a statin) Adjunct to diet to reduce elevated LDL-C in adults with mixed hyperlipidemia (in combination with fenofibrate) Reduce elevated LDL-C levels in adults and pediatric patients ≥ 10 years of age with HoFH (in combination with a statin and other LDL-C lowering therapies) Adjunct to diet for reduction of elevated sitosterol and campesterol in adults and pediatric patients ≥ 9 years of age with homozygous familial sitosterolemia
Niacin		
niacin ER ¹⁰	generic	<ul style="list-style-type: none"> Primary hyperlipidemia or mixed dyslipidemia Primary hyperlipidemia or patients with a history of coronary artery disease (CAD) and hyperlipidemia (in combination with a bile acid sequestrant) Severe hypertriglyceridemia as adjunct in patients at risk for pancreatitis Patients with a history of myocardial infarction (MI) and hyperlipidemia
niacin IR (Niacor®) ¹¹	Redmont, Avondale	<ul style="list-style-type: none"> Primary hypercholesterolemia (monotherapy or in combination with bile-acid binding resin) Hypertriglyceridemia, types IV and V hyperlipidemia for those who present with a risk of pancreatitis (adjunctive therapy)

ER = extended release; IR = immediate release; ‡ Authorized generic (AG) available.



Lipotropics, Other

Drug	Manufacturer	Indication(s)
Fibric Acids		
fenofibrate ^{¶12}	generic	As an adjunct to diet:
fenofibrate [¶] (Fenoglide®) ¹³	generic, Santarus	<ul style="list-style-type: none"> To reduce elevated LDL-C in adult patients with primary hyperlipidemia when use of recommended LDL-C lowering therapy is not possible Severe hypertriglyceridemia (TG ≥ 500 mg/dL) in adults
fenofibrate [¶] (Lipofen®) ¹⁴	Ani	
fenofibrate [¶] (Tricor®) ¹⁵	generic, Abbvie	
fenofibric acid [¶] (Fibricor®) ¹⁶	generic [‡] , Athena	As an adjunct to diet:
fenofibric acid ^{¶17}	generic	<ul style="list-style-type: none"> To reduce elevated LDL-C in adult patients with primary hyperlipidemia when use of recommended LDL-C lowering therapy is not possible Severe hypertriglyceridemia (TG ≥ 500 mg/dL) in adults
gemfibrozil (Lopid®) ¹⁸	generic, Pfizer	

Lipotropics, Other

Drug	Manufacturer	Indication(s)
Omega-3 Fatty Acids		
icosapent ethyl [§] (Vascepa®) ²¹	generic, Amarin	<ul style="list-style-type: none"> As adjunct to maximally tolerated statin therapy to reduce the risk of MI, stroke, coronary revascularization, and unstable angina requiring hospitalization in adults with elevated TG levels (≥ 150 mg/dL) and <ul style="list-style-type: none"> Established cardiovascular disease (CVD); or Diabetes mellitus and ≥ 2 additional risk factors for CVD As adjunct to diet, to reduce TG levels in adults with severe hypertriglyceridemia (TG ≥ 500 mg/dL)
omega-3 acid ethyl esters [§] (Lovaza®) ²²	generic, Waylis	<ul style="list-style-type: none"> Treatment of hypertriglyceridemia in adults with TG ≥ 500 mg/dL
Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors		
alirocumab (Praluent®) ²³	Regeneron	<ul style="list-style-type: none"> To reduce the risk of major adverse CV events (CHD death, MI, stroke, or unstable angina requiring hospitalization in adults at increased risk for these events) As adjunct to diet and exercise to reduce LDL-C in: <ul style="list-style-type: none"> Adults with hypercholesterolemia Adults and pediatric patients ≥ 8 years of age with HeFH Adults with HoFH
evolocumab (Repatha®) ²⁴	Amgen	<ul style="list-style-type: none"> To reduce the risk of major adverse CV events (CV death, MI, stroke, or unstable angina requiring hospitalization in adults at increased risk for these events) As adjunct to diet and exercise to reduce LDL-C in: <ul style="list-style-type: none"> Adults with primary hyperlipidemia Adults and pediatric patients aged ≥ 10 years with HeFH Adults and pediatric patients aged ≥ 10 years with HoFH
PCSK9-Directed Small Interfering Ribonucleic Acid (siRNA)		
inclisiran (Leqvio®) ²⁵	Novartis	<ul style="list-style-type: none"> As an adjunct to diet and exercise in adults with hypercholesterolemia, including HeFH, to reduce LDL-C

Lipotropics, Other

- Each class of non-statin lipotropics provides a unique option for use in patients who cannot reach target lipid levels on statin monotherapy or who do not tolerate statins
- While there are not outcomes data for each class, their effects on lipids profiles are clearly substantiated
- The ACC and the AHA states that these agents (e.g., ezetimibe, PCSK9 inhibitors) may be added to maximally tolerated statin therapy to lower LDL-C sufficiently to reduce ASCVD event risk in individuals with primary severe elevations of LDL-C
- Per the Endocrine Society (ES), a fibrate is considered a first-line treatment for severe and very severe hypertriglyceridemia (with fasting TG levels > 500 mg/dL)

Lipotropics, Other

- For patients with moderate to severe hypertriglyceridemia, fibrates, niacin, and omega-3 fatty acids alone or in combination with statins may be considered
- The AHA advised that initial drug monotherapy for those with FH includes high-intensity statin therapy
- If needed, the addition of ezetimibe followed by PCSK9 inhibitor, a bile acid sequestrant, or prescription strength niacin should be considered if target LDL-C is not met

Lipotropics, Other

- Per the AACE/ACE, a fibrate or omega-3 fatty acid can be considered for patients with hypertriglyceridemia who do not have established ASCVD or DM with ≥ 2 risk factors and are not at the TG goal of < 150 mg/dL with statin therapy
- All patients with severe hypertriglyceridemia (> 500 mg/dL) should receive a fibrate and/or prescription-grade omega-3 fatty acid in order to decrease the potential for acute pancreatitis
- Niacin is no longer recommended for ASCVD prevention due to lack of benefit and increased adverse effects.
- The ACC expert consensus decision pathway for the management of ASCVD risk reduction in patients with persistent hypertriglyceridemia emphasizes the necessary lifestyle interventions and consideration of fibrates and prescription-grade omega-3 fatty acids

Lipotropics, Other

- They also note that fibrates provide benefit as monotherapy but not when combined with statins
- Bile acid sequestrants can be used in combination with statins, and are effective in lowering LDL-C and at producing a small increase in HDL-C
- Their effect on decreasing TG levels is between 0% and 25%
- Patients generally have poor compliance to bile acid sequestrants because of their side effect profile
- ACC's recommendations on bile acid sequestrants is to use only as a secondary alternative in patients intolerant to ezetimibe

Lipotropics, Other

- Fibric acids lower TG levels and raise HDL-C levels to a greater extent than do the statins, but as a group have less favorable effects on clinical CV outcomes
- They should be considered as an alternative agent to the statins for specific lipid disorders or can be used as add-on therapy
- Gemfibrozil has demonstrated reductions in CHD risk primarily in subsets of patients with high TG, low HDL-C, and characteristics of metabolic syndrome

Lipotropics, Other

- Niacin has been shown to reduce major coronary events
- Compared to immediate-release niacin (Niacor), niacin extended-release (ER) may increase compliance and reduce the incidence of flushing
- Over the counter (OTC) preparations of niacin may lack nicotinic acid or be associated with an increased risk of hepatotoxicity
- Ezetimibe reduces LDL-C, both when given alone and in combination with a statin
- The IMPROVE-IT study reported lower CV mortality and morbidity when ezetimibe was added to statin (simvastatin) therapy as compared to a statin alone

Lipotropics, Other

- The ACC consensus decision pathway states HoFH patients, with or without clinical ASCVD, may be candidates for Juxtapid if unable to reach LDL-C goals despite maximally tolerated statin therapy with or without ezetimibe, a PCSK9 inhibitor, and/or bempedoic acid
- Lovaza and Vascepa reduce TG in patients with very high TGs (> 500 mg/dL)
- Vascepa contains only EPA; Lovaza contains both EPA and DHA
- A Science Advisory by the AHA states that omega-3 polyunsaturated fatty acid (PUFA) supplementation is reasonable in patients with CHD to reduce CHD-related mortality

Lipotropics, Other

- Alirocumab (Praluent) and evolocumab (Repatha) both have demonstrated significant efficacy in LDL-C lowering
- The AHA advises that PCSK9 inhibitors can be added to high-intensity statin plus ezetimibe therapy in patients with FH when dual therapy does not result in desired LDL-C goal after 3 months of adherent therapy
- The FOURIER and ODYSSEY OUTCOMES studies reported a 15% reduction in the composite of CV outcomes when Repatha or Praluent were added to optimal statin therapy

Lipotropics, Other

- Bempedoic acid offers another option for those requiring additional cholesterol lowering therapy for patients who are not at goal with diet and maximally tolerated statin therapy
- Bempedoic acid carries risks for hyperuricemia and tendon rupture
- AACE/ACE recommend treatment intensification with the addition of other LDL-C lowering agents (e.g., PCSK9 inhibitors, ezetimibe, colesevelam, bempedoic acid) as needed to reach treatment goals
- The ACC states bempedoic acid can be added for patients who do not achieve LDL-C goals despite the addition of other non-statin agents

Lipotropics, Other

- The CLEAR Outcomes trial demonstrated that bempedoic acid was associated with lower risk of MACE compared to placebo in patients who were unable or unwilling to take a statin and had or were at high risk for CVD
- Evincumab (Evkeeza) has shown to decrease LDL-C by almost half as concomitant therapy in a phase 3 trial after 24 weeks
- The effects of evincumab on CV morbidity and mortality have not been established
- The ACC consensus decision pathway states HoFH patients, with or without clinical ASCVD, may be candidates for evincumab if unable to reach LDL-C goals despite maximally tolerated statin therapy with or without ezetimibe, a PCSK9 inhibitor, and/or bempedoic acid

Lipotropics, Other

- Data from 3 placebo-controlled trials demonstrated a favorable safety profile and a significant reduction in LDL-C by 48% to 52% with inclisiran (Leqvio) versus placebo as add on to maximally tolerated statin therapy (with or without other lipid-modifying therapy)
- Data are not yet available regarding the effect of inclisiran on CV morbidity and mortality
- The ACC consensus decision pathway states inclisiran can be considered for patients with poor adherence to PCSK9 inhibitors or those who cannot self-inject

Lipotropics, Other

Clinical/Product Updates:

- Per The 2025 AACE clinical practice guideline, for patients who do not achieve LDL-C goals with either a statin +/- ezetimibe, additional medications may be considered:
 - Alirocumab or evolocumab for ASCVD or high-risk patients
 - Inclisiran as an option with limited evidence
 - Bempedoic acid for statin-intolerant individuals
- For hypertriglyceridemia (TG 150–499 mg/dL) in patients with ASCVD or increased risk, icosapent ethyl (EPA only) may be recommended as add-on therapy
- The guideline advises against adding niacin for ASCVD prevention due to lack of benefit and increased adverse effects

Lipotropics, Other

Clinical/Product Updates:

- FDA reported manufacture of Lopid 600 mg tablet will be discontinued. Generics remain available
- FDA approved an expansion of Juxtapid's indication to include patients ≥ 2 years old with homozygous familial hypercholesterolemia (HoFH) and approved a new 2 mg strength capsule for peds; previously, it was only indicated for use in adults
- FDA approved a new indication for Tryngolza to reduce TGs and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG; TG ≥ 500 mg/dL)
- Lerochol has been approved as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including HeFH



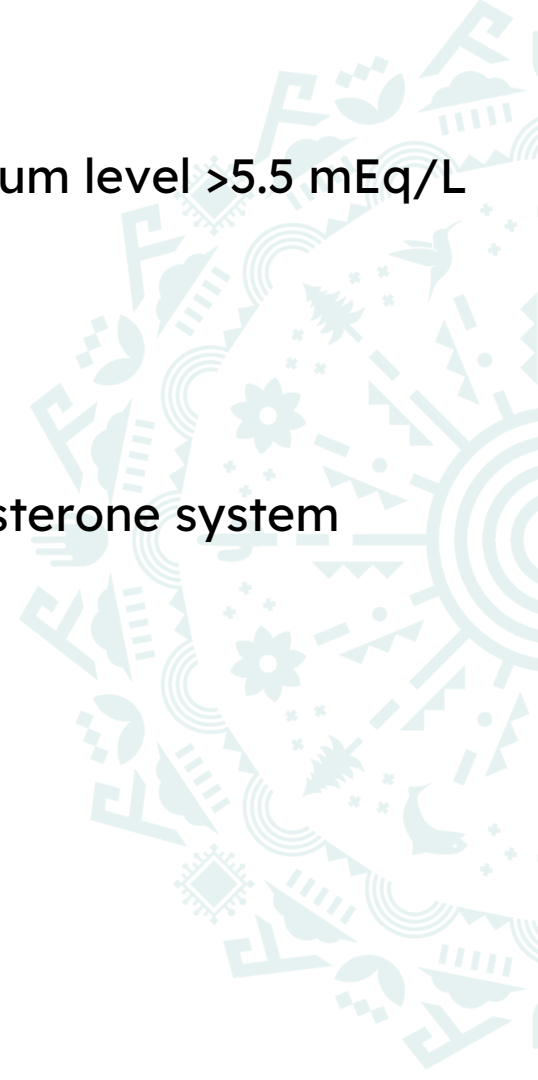
Potassium Binders

Potassium Binders

Drug	Manufacturer	Indication(s)
patiromer (Veltassa®)	Relypsa/Vifor	Treatment of hyperkalemia in adults and pediatric patients ≥ 12 years of age. <i>Limitation of use:</i> should not be used as an emergency treatment for life-threatening hyperkalemia because of delayed onset of action
sodium polystyrene sulfonate (Kionex®, SPS®)	ANI generic	Treatment of hyperkalemia. <i>Limitation of use:</i> should not be used as an emergency treatment for life-threatening hyperkalemia because of delayed onset of action
sodium zirconium cyclosilicate (Lokelma®)	AstraZeneca	Treatment of hyperkalemia in adults

Potassium Binders

- Hyperkalemia is generally defined as a serum potassium level >5.5 mEq/L
- Common causes of hyperkalemia include:
 - Acute or chronic kidney disease
 - Diabetes and uncontrolled hyperglycemia
 - Heart failure
 - Medications affecting the renin-angiotensin-aldosterone system (RAAS)
- Hyperkalemia can result in:
 - Muscle weakness or paralysis
 - Neurologic impairment
 - Cardiac conduction abnormalities
 - Bradyarrhythmias
 - Metabolic acidosis



Potassium Binders

- Potassium binders are approved for the treatment of hyperkalemia only in non-emergency treatment conditions due to their delayed onset of action
- All agents in this class should be avoided in patients with bowel disease due to the potential effect on gastrointestinal (GI) motility
- Sodium polystyrene sulfonate (SPS) is associated with perforation, increased risk of serious GI toxicity, and intestinal necrosis
- All are available as powders for suspension, which require reconstitution in liquid for oral administration; SPS may also be administered rectally

Potassium Binders

- The dose is dependent on serum potassium levels and response and should be adjusted to maintain normokalemia
- Head-to-head and rigorous, high-quality, double-blind, randomized clinical trials are limited in this class
- The effectiveness and safety of chronic sodium polystyrene sulfonate use are not well-established in published literature
- Recommendations from professional organizations guiding treatment of chronic hyperkalemia are lacking



Sickle Cell Anemia

Sickle Cell Anemia

Drug	Manufacturer	Indication(s)
crizanlizumab-tmca (Adakveo®)	Novartis	To reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients ages ≥ 16 years with sickle cell disease (SCD)
exagamglogene autotemcel (Casgevy™)	Vertex	Treatment of patients ages ≥ 12 years with: <ul style="list-style-type: none"> ▪ SCD with recurrent VOCs ▪ Transfusion-dependent β-thalassemia (TDT)
hydroxyurea capsule (Droxia®)	Waylis	To reduce the frequency of painful crises and to reduce the need for blood transfusions in adult patients with sickle cell anemia with recurrent moderate to severe painful crises
hydroxyurea tablet (Siklos®)	Medunik USA	To reduce the frequency of painful crises and to reduce the need for blood transfusions in adults and pediatric patients ages ≥ 2 years with sickle cell anemia with recurrent moderate to severe painful crises
hydroxyurea solution (Xromi®)	Nova	To reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients ages ≥ 6 months with sickle cell anemia with recurrent moderate to severe painful crises
L-glutamine (Endari®)	generic, Emmaus	To reduce the acute complications of SCD in adult and pediatric patients ages ≥ 5 years
lovotibeglogene autotemcel (Lyfgenia®)	Bluebird Bio	Treatment of patients ages ≥ 12 years with SCD with a history of vaso-occlusive events (VOEs)



Sickle Cell Anemia

- Sickle cell disease (SCD) affects about 100,000 people in the US and is most common among African Americans
- (SCD) is a genetic red blood cell (RBC) disorder resulting in the production of abnormal, sickle-shaped hemoglobin S (HbS)
- Sickle cell anemia (homozygous sickle mutation; HbSS), is the most common and most severe form of SCD
- Vaso-occlusion crises (VOCs) occur when abnormal RBCs adhere to blood vessel walls, resulting in blockage of small blood vessels, reduced oxygen flow to tissues, and organ damage
- Life expectancy is typically reduced by approximately 20–30 years

Sickle Cell Anemia

- According to the American Society of Hematology (ASH) 2020 guidelines, there is lack of comparative-effectiveness data between hydroxyurea and other disease-modifying therapies and chronic transfusions to make a recommendation on the use of these agents for acute and chronic pain
- Hydroxyurea was recommended by the National Heart, Lung, and Blood Institute's (NHLBI) in their 2014 guidelines to treat associated pain that interferes with daily activities
- Clinical trials with crizanlizumab-tmca (Adakveo), hydroxyurea, and L-glutamine (Endari) reported a reduction in the rate of VOCs
- Hematopoietic stem cell transplant (HSCT) remains the only proven cure, and emerging gene therapies are offering new treatment possibilities



New Drug Reviews

Hind Douiki, Pharm.D.

New Drug Reviews

- Yuviwel (navepegritide)
- Wainua (eplontersen)
- Idvynso (doravirine/islatravir)
- Bysanti (milsaperidone)
- Baxfendy (baxdrostat)
- Xocova (ensitrelvir)
- Lynavoy ((linerixibat)

Yuviwel (navepegritide)

- Indicated to increase linear growth in pediatric patients ≥ 2 years of age with achondroplasia with open epiphyses
- Approved under accelerated approval based on an improvement in annualized growth velocity
- Dosage is based on body weight and is administer SC once-weekly
- Growth should be periodically monitored and dose adjusted according to body weight
- Available in 1.3 mg, 2.8 mg, and 5.5 mg injection as a lyophilized powder in single dose vial for reconstitution
- Not recommended for patients with moderate or severe renal impairment ($\text{eGFR} < 60 \text{ mL/min/1.73 m}^2$)

Yuviwel (navepegritide)

- Warning: Risk of Low Blood Pressure
- Adverse reactions: vomiting, injection-site reaction, pain in extremity, and nausea
- ApproaCH was a Phase 3, randomized, double-blind, and placebo-controlled trial
- 84 treatment-naïve pediatric patients aged 2 to 11 years with genetically confirmed achondroplasia and open epiphyses were included in the study
- Patients were randomized to receive either subcutaneous Yuviwel 0.1 mg/kg or a placebo once weekly

Yuviwel (navepegritide)

- At week 52, treatment with Yuviwel showed a significantly higher annualized growth velocity (AGV) compared to the placebo group (5.9 vs 4.4 cm/year; difference, 1.5 [95% CI, 1.0-1.9]; $P < .0001$)
- Yuviwel also demonstrated a greater increase from baseline in achondroplasia-specific height Z-scores (0.3 vs 0.0; difference, 0.3 [95% CI, 0.2-0.4]; $P < .0001$) and CDC height Z-scores (0.1 vs -0.2; difference, 0.3 [95% CI, 0.1-0.5]) vs placebo

Wainua (eplontersen)

- Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
- The recommended dosage is 45 mg administered by subcutaneous injection once monthly
- Available as 45 mg/0.8 mL in a single-dose autoinjector and prefilled syringe
- Warning: Reduced Serum Vitamin A Levels and Recommended Supplementation
- Adverse reactions: vitamin A decrease and vomiting

Wainua (eplontersen)

- The approval was based on data from the randomized, open-label, multicenter phase 3 NEURO-TTRansform trial
- The study assessed the efficacy and safety of Wainua in adults with hereditary transthyretin-mediated amyloidosis
- Participants were randomly assigned 6:1 to receive either Wainua 45mg SC once every 4 weeks (n=144) or inotersen 284mg SC once weekly (n=24)
- According to 35-week interim analysis, treatment with Wainua resulted in a statistically significant and clinically meaningful change from baseline in the modified Neuropathy Impairment Score +7 (mNIS+7; a measure of neuropathic disease progression) (mean least squares [LS] treatment difference, -9.0 [95% CI, -13.5, -4.5]; $P < .001$)

Wainua (eplontersen)

- Secondly, Wainua achieved positive results in the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score (mean LS treatment difference, -11.8 [95% CI, -16.8, -6.8]; $P < .001$), compared with the external placebo arm
- patients who received Wainua demonstrated similar improvements in mNIS+7 and Norfolk QoL-DN score across subgroups including age, sex, race, region, Val30Met variant status, and disease stage
- Consistent and sustained benefits in Wainua-treated patients were also observed in mNIS+7 and Norfolk QoL-DN score at 66 and 85 weeks from baseline

Wainua (eplontersen)

- CARDIO-TTRansform was a global, randomized, double-blind, placebo-controlled Phase 3 study
- It evaluated Wainua in adults with wild-type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM) receiving available standard of care (SOC)
- At baseline, 57% of patients in each arm were receiving transthyretin (TTR) stabilizer treatment
- Participants (N=1432) were randomly assigned to receive subcutaneous injections of either Wainua 45mg or placebo once every 4 weeks

Wainua (eplontersen)

- During the trial, an additional 24% of patients in each arm initiated a TTR stabilizer
- The primary endpoint was the composite outcome of cardiovascular (CV) mortality and recurrent CV clinical events from baseline to week 140
- Compared with placebo, the addition of Wainua to SOC did not result in a statistically significant reduction in the risk for the composite outcome of CV mortality and recurrent CV events
- No treatment effect was reported among patients who were on TTR stabilizer therapy at baseline
- In a prespecified subgroup analysis of those who received Wainua monotherapy, a nominally significant result was observed (hazard ratio, 0.71) for the primary endpoint vs placebo

Idvynso (doravirine/islatravir)

- Indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen (ARR) in those who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable ARR with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine
- Dosage is one tablet taken orally once daily
- Dosage adjustment is required for patients taking concomitant rifabutin
- Available as 100 mg doravirine and 0.25 mg islatravir tablet
- Warning: Severe skin reactions

Idvynso (doravirine/islatravir)

- **Contraindications:**
 - Co-administration with drugs that are strong cytochrome P450 3A enzyme inducers
 - Co-administration with lamivudine (3TC) or emtricitabine (FTC)
- **Adverse reactions:** diarrhea, dizziness, fatigue, abdominal distension, headache, and weight increase
- The approval was based on data from 2 randomized, active-controlled, noninferiority trials, Trial 051 (N=551) and Trial 052 (N=513) in virologically-suppressed patients with HIV

Idvynso (doravirine/islatravir)

- To be eligible for inclusion, patients had to be stably suppressed on their baseline HIV regimen for at least 3 months prior to enrollment with no history of treatment failure
- In Trials 051 (N=551) and 052 (N=513), study participants were randomly assigned 2:1 to either:
 - Switch to once-daily Idvynso (Trial 051: n=366; Trial 052: n=342)
 - Or remain on current baseline therapy (Trial 051: antiretroviral therapy [ART; n=185]; Trial 052: bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF; n=171])
- Findings from Trial 051 showed that 1% of participants who were treated with Idvynso had a viral load of ≥ 50 copies/mL compared with 5% of patients who continued on baseline ART at week 48 (difference, -3.6% [95% CI, -7.8, -0.8])

Idvynso (doravirine/islatravir)

- 96% of patients who switched to Idvynso maintained viral suppression (HIV-1 RNA <50 copies/mL) at week 48 vs 92% of those who continued on baseline ART
- At week 48, the mean increase from baseline in CD4+ T-cell counts in was 5 cells/mm³ in the Idvynso group vs 18 cells/mm³ in the baseline ART group
- In Trial 052, 1% of patients in both the Idvynso arm and the BIC/FTC/TAF arm had a viral load of ≥ 50 copies/mL at week 48 (difference, 0.9% [95% CI, -1.9%, 2.9%])
- The proportion of patients maintaining viral suppression at week 48 was 92% and 94%, respectively
- The mean increase in CD4+ T-cell counts from baseline was 30 and 28 cells/mm³, respectively

Bysanti (milsaperidone)

- Indicated for:
 - Treatment of schizophrenia in adults
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
- After the titration, the recommended maintenance dosage for
- Schizophrenia is 6 to 12 mg twice daily
- Bipolar mania is 12 mg twice daily
- Available as 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg tablets
- Contraindication: Known hypersensitivity to milsaperidone or the inactive ingredients in Bysanti
- Boxed Warning: Increased Mortality In Elderly Patients With Dementia-related Psychosis

Bysanti (milsaperidone)

Warnings:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-related Psychosis
- QTc Interval Prolongation
- Neuroleptic Malignant Syndrome (NMS)
- Tardive Dyskinesia
- Metabolic Changes
- Orthostatic hypotension and Syncope
- Seizures
- Leukopenia, Neutropenia, and Agranulocytosis
- Priapism
- Potential for Cognitive and Motor Impairment
- Intraoperative Floppy Iris Syndrome (IFIS)



Bysanti (milsaperidone)

- Adverse Reactions:
 - **Schizophrenia:** dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased
 - **Bipolar mania:** tachycardia, dizziness, dry mouth, hepatic enzymes increased, nasal congestion, weight increased, hypotension, and somnolence
- Drug Interactions:
 - Strong CYP2D6 Inhibitors and/or Strong CYP3A4 Inhibitors – dosage should be reduced
 - Drugs that Lower Blood Pressure - concomitant administration with alpha-adrenergic blocking agents should be avoided and lowering the dosage of other drugs that lower blood pressure should be considered

Bysanti (milsaperidone)

- The FDA approved Bysanti based on pharmacokinetic bioequivalence studies to bridge data from its active parent drug/metabolite, Fanapt (iloperidone)
- Vanda Pharmaceuticals demonstrated that oral administration of Bysanti rapidly interconverts to iloperidone and satisfies standard bioequivalence parameters (90% confidence intervals within 80%–125%) across single-dose, multiple-dose, and steady-state evaluations
- The submission leveraged 4 foundational clinical studies for iloperidone covering adults exposed in acute schizophrenia trials, a bipolar I disorder manic/mixed episode trial, and a schizophrenia relapse prevention trial

Bysanti (milsaperidone)

- Results showed in patients with schizophrenia, iloperidone significantly improved symptoms, as measured by the Positive and Negative Syndrome Scale and the Brief Psychiatric Rating Scale total score, and extended the time to relapse or impending relapse vs placebo
- In patients with bipolar I disorder, iloperidone led to greater improvements in symptoms based on the Young Mania Rating Scale

Baxfendy (baxdrostat)

- Indicated for the treatment of hypertension, in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents
- Recommended dosage is 2 mg orally once daily
- For patients at increased risk of hyperkalemia or hyponatremia, the recommended dosage is 1 mg once daily
- Available as 1 mg and 2 mg tablets
- Warnings: Hyperkalemia; Hyponatremia
- Adverse Reaction: hyperkalemia
- Drug Interactions
 - Drugs That Increase Serum Potassium
 - Strong and moderate CYP3A inducers

Baxfendy (baxdrostat)

- The approval was based on the phase 3 BaxHTN trial
- It evaluated Baxfendy in adults with a systolic blood pressure (SBP) of ≥ 140 mmHg and < 170 mmHg who were already taking at least 2 antihypertensive medications, including a diuretic
- To be eligible, patients also had to have an estimated glomerular filtration rate (eGFR) ≥ 45 mL/min/1.73m² and a serum potassium of ≥ 3.5 mEq/L and < 5.0 mEq/L
- After completing a 2-week placebo run-in period, participants (N=794) were randomly assigned to receive Baxfendy 1mg (n=264), Baxfendy 2mg (n=266), or placebo (n=263) once daily alongside background therapy
- The primary endpoint was the change from baseline in seated SBP at week 12

Baxfendy (baxdrostat)

- Results showed both Baxfendy doses led to statistically significant reductions in mean SBP compared with placebo at week 12 (placebo-adjusted reduction: 1mg: -8.7mmHg [95% CI, -11.5, -5.8]; 2mg: -9.8mmHg [95% CI, -12.6, -7.0]; both $P < .0001$)
- Baxfendy 1mg and 2mg also significantly reduced mean diastolic blood pressure vs placebo (placebo-adjusted reduction: 1mg: -3.3mmHg [95% CI, -5.2, -1.4]; $P = .0008$; 2mg: -3.9mmHg [95% CI, -5.7, -2.0]; $P < .0001$)
- Following the initial 12-week double-blind period, study participants entered a 12-week, open-label phase
- Patients previously receiving Baxfendy 2mg continued their dose
- Participants on Baxfendy 1mg or placebo were randomly reassigned to receive either Baxfendy 2mg or standard of care

Baxfendy (baxdrostat)

- Upon completion of the open-label phase, the patients on Baxfendy 2mg (N=257) were again rerandomized 2:1 to either continue Baxfendy 2mg (n=172) or switch to placebo (n=85) once daily for an 8-week withdrawal period
- Results showed treatment with Baxfendy 2mg maintained blood pressure reductions during the randomized withdrawal phase
- The mean change in SBP was -3.7mmHg (95% CI, -5.5, -1.9) in the Baxfendy 2mg arm and +1.4mmHg (95% CI, -1.2, 4.0) in the placebo arm (mean difference, -5.1mmHg [95% CI, -8.3, -1.9]; $P = .002$)

Xocova (ensitrelvir)

- Indicated for post-exposure prophylaxis (PEP) of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19
- Pregnancy status of females of reproductive potential should be verified prior to initiating Xocova
- Should be initiated as soon as possible and within 72 hours following contact with an individual who has COVID-19
- Dosage is 375 mg orally on day 1 and 125 mg orally on days 2 to 5

Available as 125 mg tablet

Xocova (ensitrelvir)

- Contraindications:
 - History of clinically significant hypersensitivity reactions to ensitrelvir or any other components of the product
 - Co-administration with drugs primarily metabolized by CYP3A
 - Co-administration with strong CYP3A inducers
- Warnings:
 - Embryofetal toxicity
 - The concomitant use with certain other drugs may result in potentially significant drug interactions
 - Hypersensitivity reactions

Xocova (ensitrelvir)

- Adverse Events: headache, diarrhea, and cough
- The approval for Xocova for COVID-19 PEP was based on data from the randomized, double-blind, placebo-controlled, multinational Phase 3 SCORPIO-PEP trial
- It enrolled 2387 individuals ≥ 12 years old who had a negative screening test for SARS-CoV-2
- All participants were also living in a household with an index patient for the duration of the study
- Participants were randomly assigned 1:1 to receive Xocova 375mg on day 1 followed by 125mg on days 2 through 5 or matching placebo
- Treatment was initiated within 3 days of when the infected household member began showing symptoms

Xocova (ensitrelvir)

- Findings from the modified intention-to-treat (mITT) population excluded patients subsequently found to be SARS-CoV-2 RT-PCR-positive at baseline (n=2041)
- Results showed Xocova significantly reduced the likelihood of developing symptomatic COVID-19 following household exposure by 67% compared with placebo (relative risk ratio, 0.33 [95% CI, 0.22-0.49]; $P < .0001$)
- In the ITT population (all participants including those subsequently found to be SARS-CoV-2 positive at baseline; secondary endpoint), the risk reduction with Xocova vs placebo was 57% (relative risk ratio, 0.43 [95% CI, 0.32-0.59]; $P < .0001$)

Lynavoy (limerixibat)

- Indicated for the treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adults
- Recommended dosage is 40 mg taken orally twice daily
- Available as 40 mg tablet
- Use should be avoided in patients with decompensated cirrhosis or those with prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)
- Warnings:
 - Liver Test Elevations
 - Diarrhea
 - Fat-Soluble Vitamin Deficiency

Lynavoy (linerixibat)

- Adverse reactions: diarrhea, abdominal pain, nausea, increased ALT, hemorrhage, increased AST, headache, dyspepsia, gastroesophageal reflux disease, abdominal distension, dizziness, and arthralgia
- GLISTEN was a global, double-blind, randomized, placebo-controlled phase 3 study
- It evaluated 238 adult patients with primary PBC and moderate-to-severe itch
- Participants were randomly assigned to receive oral Lynavoy 40 mg twice daily or placebo
- The primary endpoint was the change from baseline in monthly itch score, assessed using a numerical rating scale (NRS) from 0 (no itching) to 10 (worst imaginable itching), over 24 weeks

Lynavoy (linexibat)

- Findings showed treatment with Lynavoy led to a statistically significant improvement in pruritus compared with placebo (least squares mean difference in monthly itch score, -0.72 [95% CI, -1.15, -0.28]; $P = .001$)
- Lynavoy was also associated with significant improvements in key secondary endpoints vs placebo, including pruritus-related sleep interference over 24 weeks (mean difference in monthly sleep score, -0.53 [95% CI, -0.98, -0.07]; $P = .024$)

Break and Executive Session





Public Therapeutic Class Votes



Biosimilar Update



Meeting Adjournment

2027 Meeting Dates:
January 26
May 18
October 19