Commissioner for the Department for Medicaid Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner of the Department for Medicaid Services (DMS) based on the Drug Review and Options for Consideration document prepared for the Pharmacy and Therapeutics (P&T) Advisory Committee's review on **September 15, 2022,** and the resulting official recommendations.

New Products to Market

Quviviq™-Non-prefer in the PDL class: *Sedative Hypnotic Agents*

Length of Authorization: 6 months initial; 1 year renewal

- Daridorexant (Quviviq™) is an orexin receptor antagonist indicated in the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Criteria for Approval:

Initial Approval Criteria

- Approval of non-preferred agents requires trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred agent, unless otherwise specified.

Maximum Duration: 60 days

Age Limit: ≥ 18 years

Quantity Limit: 30 tablets/30 days

Igalmi™- Non-prefer in the PDL class: *Sedative Hypnotic Agents*

Length of Authorization: 12 months

- Dexmedetomidine (Igalmi™) is an alpha-2 adrenergic agonist indicated in adults for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.

Criteria for Approval:

Initial Approval Criteria

- Patient has agitation associated with a confirmed diagnosis of schizophrenia or bipolar disorder, defined as meeting DSM-5 criteria for schizophrenia, schizoaffective, or schizophreniform disorder or bipolar I or II disorder; AND
- Agitation is NOT due to acute intoxication; AND
- Prescriber attestation that patient will be monitored by a healthcare provider, including an assessment of vital signs and alertness to prevent falls and syncope; AND
- Patient is NOT taking medications known to prolong the QT interval; AND

- Prescriber attestation that patient has been advised to avoid activities requiring mental alertness for at least 8 hours following administration.

Renewal Criteria

- Patient must continue to meet the above criteria; AND
- Prescriber attestation of response (patient not requiring alternative agents following treatment of mild to moderate agitation); AND
- Patient has not experienced any treatment-restricting adverse effects (e.g., syncope, orthostatic hypotension, fall, QT prolongation, symptomatic bradycardia).

Age Limit: ≥18 years

Quantity Limit:
120 mcg film: 2 per day
180 mcg film: 2 per day

* Approval requires trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 2 preferred agents (may include any preferred benzodiazepine or antipsychotic).

Drug Class	Preferred Agents	Non-Preferred Agents
Sedative Hypnotic Agents	temazepam 15 mg, 30 mg MD, QL zolpidem MD, QL	*Ambien® MD, QL* *Ambien CR® MD, QL* *Belsomra® MD, QL* *Dayvigo™ MD, QL* *Doral® MD, QL* *doxepin QL (generic Silenor®)* *Edluar® CC, MD, QL* *estazolam MD, QL* *eszopiclone MD, QL* *flurazepam MD, QL* *Halcion® MD, QL* *Hetlioz® CC, QL* *Hetlioz LQ® CC, QL* *Igalmi™ AE, CC, QL* *Intermezzo® MD, QL* *Lunesta™ MD, QL* *Quviviq™ AE, MD, QL* *ramelteon CC, MD, QL* *Restoril® MD, QL* *Rozerem® CC, MD, QL* *Silenor® QL* *temazepam 7.5 mg, 22.5 mg MD, QL* *triazolam MD, QL* *zaleplon MD, QL* *zolpidem ER MD, QL* *zolpidem SL MD, QL*

Ibsrela®- Non-preferred in the PDL class: *GI Motility Agents*

Length of Authorization: 1 year

- Tenapanor (Ibsrela) is a locally acting, sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for irritable bowel syndrome with constipation (IBS-C) in adults.

Criteria for Approval:

Initial Approval Criteria

- Patient does NOT have known or suspected mechanical GI obstruction; AND
- Patient does NOT have severe diarrhea; AND
- Patient has failed on 1 of the following regimens:
  - Osmotic laxatives; OR
  - Antispasmodics; AND
- Patient has had at least a 1-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 2 preferred agents.

Age Limit: ≥ 18 years
Quantity Limit: 60 tablets/ 30 days

Drug Class	Preferred Agents	Non-Preferred Agents
GI Motility Agents	Amitiza® CC, AE, QL Linzess® CC, AE, QL Movantik® CC, AE, QL	*alosetron* CC, AE, QL *Ibsrela®* CC, AE, QL *Lotronex®* CC ,AE, QL *lubiprostone* AE, QL *Motegrity™* AE, QL *Relistor®* CC, AE, QL *Symproic®* CC , AE, QL *Trulance™* AE, QL *Viberzi®* CC, AE, ,QL

Mounjaro™ - Non-preferred in the PDL class: *Diabetes: GLP-1 Receptor Agonists*

Length of Authorization: 1 year

- Tirzepatide (Mounjaro) is a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

Criteria for Approval:

Initial Approval Criteria

- Diagnosis of Type II Diabetes Mellitus; AND
- Trial and failure, intolerance or contraindication to metformin. OR
- Diagnosis of chronic kidney disease (ICD-10 Group N18) AND trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; OR
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD); OR
- Diagnosis of heart failure with reduced ejection fraction AND trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor. AND

- Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of at least 3-month therapy with 1 preferred GLP-1 agent, unless otherwise specified.

Age Limit: None

Quantity Limit: 4 pens per 28 days

Drug Class	Preferred Agents	Non-Preferred Agents
Diabetes: GLP-1 Receptor Agonists	Byetta® CC, QL Bydureon® Pen CC, QL Ozempic® CC, AE, QL Victoza® CC, QL	*Adlyxin™ AE,QL* *Bydureon® BCise™* *Mounjaro™ CC, QL* *Rybelsus® AE, QL* *Soliqua™ CC, AE, QL* *Trulicity™ QL* *Xultophy® CC, AE, QL*

Vtama® - Non-preferred in the PDL class: *Topical Psoriasis Agents*

Length of Authorization: 1 year

- Tapinarof (Vtama) cream is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults

Criteria for Approval:

- Patient must have an adequate trial and failure, contraindication or intolerance, of at least two preferred medications within the last 90 days.
- Patient has NOT experienced any treatment-restricting adverse effects

Age Limit: ≥18 years

Quantity Limit: 1 tube per 30 days

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Psoriasis Agents	calcipotriene ointment, solution Dovonex® cream salicylic acid urea cream QL, foam, lotion	*Bensal HP®* *calcipotriene cream, foam* *calcipotriene/betamethasone* *calcitriol ointment* *Duobrii™* *Enstilar® MD, AE* *Kerafoam™* *Salex™* *Sorilux™* *Taclonex®* *Uramaxin®* *Uramaxin® GT* *Vectical™* *Vtama® AE, QL*

Camzyos™- Non-PDL class

Length of Authorization: 1 year

- Mavacamten (Camzyos) is a reversible selective cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class 2 to class 3 obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

Criteria for Approval:

Initial Approval Criteria

- Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM) consistent with current guidelines (e.g., American College of Cardiology Foundation/American Heart Association, European Society of Cardiology guidelines); AND
- Patient has New York Heart Association (NYHA) Class 2 or Class 3 disease; AND
- Patient has documented left ventricular ejection fraction (LVEF) ≥ 55%; AND
- Patient will be monitored for LVEF, Valsalva left ventricular outflow tract (LVOT) gradient assessment, and heart failure symptoms); AND
- Patient will avoid concomitant use with moderate to strong CYP2C19 inhibitors, strong CYP3A4 inhibitors, and moderate to strong CYP2C19 and CYP3A4 inducers (e.g., carbamazepine, cimetidine, esomeprazole, omeprazole, phenobarbital, phenytoin, rifampin, St. John's wort); AND
- Patient will avoid concomitant dual therapy with a beta-blocker and calcium channel blocker or monotherapy with disopyramide or ranolazine; AND
- For females of childbearing potential, a pregnancy test is performed before starting therapy; AND
- Mavacamten is prescribed by or in consultation with a cardiologist; AND
- Patient must have an adequate trial and failure of ≥ 1 beta-blocker.

Renewal Criteria

- Patient must continue to meet the above criteria (not including prerequisite therapy); AND
- Patient must have disease improvement and/or stabilization of disease from baseline (e.g., at least 1 NYHA class decrease, ≥ 1.5 mL/kg/min in pVO2 increase or ≥ 3 mL/kg/min in pVO2 without NYHA class worsening); AND
- Patient has NOT have experienced any treatment-restricting adverse effects (e.g., heart failure, LVEF < 50%); AND
- Patient will continue to be monitored for LVEF, Valsalva LVOT gradient, and heart failure symptoms.

Age Limit: Patient is ≥ 18 years of age

Quantity Limit: 30 capsules/ 30 days

Full Class Reviews

Ace Inhibitors

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 distinct combinations should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ace Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Ace Inhibitors	benazepril enalapril solution (Amneal) lisinopril quinapril ramipril	*Accupril®* *Altace®* *captopril* *enalapril solution* *Epaned™ CC* *fosinopril* *Lotensin®* *moexipril* *perindopril* *Prinivil®* *Qbrelis™ CC, QL* *trandolapril* *Vasotec®* *Zestril®*

Anticonvulsants: Second Generation

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Anticonvulsants: Second Generation* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Anticonvulsants: Second Generation	Banzel® CC, QL Gabitril® QL lacosamide solution, tablets QL lamotrigine chewable tablets, tablets	*Briviact® CC, QL* *Diacomit™ CC, QL* *Elepsia® XR QL* *Epidiolex™ CC*

Drug Class	Preferred Agents	Non-Preferred Agents
	(except dose packs) levetiracetam ER QL levetiracetam solution, tablets QL Sabril® CC, QL topiramate QL zonisamide QL	*Eprontia™* *Fintepla® QL* *Fycompa™ QL* *Keppra® solution, tablets QL* *Keppra XR® QL* *Lamictal®* *Lamictal ODT®* *Lamictal® XR™ QL* *lamotrigine dose packs* *lamotrigine ER QL* *lamotrigine ODT* *Qudexy® XR QL* *rufinamide QL* *Spritam QL* *tiagabine QL* *Topamax® QL* *topiramate ER QL* *Trokendi XR™ QL* *vigabatrin* *Vimpat® QL* *Xcopri® CC, QL*

Antidepressants: Tricyclics

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Antidepressants: Tricyclics* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Antidepressants: Tricyclics	amitriptyline clomipramine doxepin concentrate, capsules imipramine hydrochloride mirtazapine nortriptyline capsule	*amoxapine* *Anafranil®* *desipramine* *doxepin tablets* *imipramine pamoate* *maprotiline* *Norpramin®* *nortriptyline solution* *Pamelor®* *protriptyline* *Remeron®*

Drug Class	Preferred Agents	Non-Preferred Agents
		trimipramine

Dopamine Receptor Agonists

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Dopamine Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee.

Note: Allow grandfathering of members using agents moving to non-preferred. Members may remain on their current product/regimen without (re)trial of a preferred agent.

Drug Class	Preferred Agents	Non-Preferred Agents
Dopamine Receptor Agonists	pramipexole ropinirole	bromocriptine *Mirapex® ER* *Neupro®* *Parlodel®* *pramipexole ER* *ropinirole ER*

Antipsychotics: Injectable

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Antipsychotics: Injectable* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Antipsychotics: Injectable	Abilify Maintena™ CC, QL Aristada ER™ CC, QL Aristada Initio™ CC, QL fluphenazine decanoate CC, QL Geodon® injection CC, QL haloperidol decanoate CC, QL haloperidol lactate CC, QL Invega® Hafyera CC, QL Invega® Sustenna® CC, QL Invega Trinza™ CC, QL	*Haldol® Decanoate QL* *Haldol® Lactate QL* *ziprasidone injection QL* *Zyprexa® QL* *Zyprexa® Relprevv QL*

Drug Class	Preferred Agents	Non-Preferred Agents
	olanzapine CC, QL Perseris ER™ CC Risperdal® Consta® CC, QL	

Beta Blockers

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Beta Blockers* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Beta-Blockers	atenolol bisoprolol metoprolol tartrate metoprolol succinate ER nadolol nebivolol propranolol propranolol ER	*acebutolol* *betaxolol* *Bystolic™* *Corgard®* *Hemangeol™* *Inderal® LA* *Inderal® XL* *InnoPran XL®* *Kapspargo™* *Lopressor®* *pindolol* *Tenormin®* *timolol* *Toprol XL®*

Calcium Channel Blockers (Non-DHP)

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the Calcium Channel Blockers (Non-DHP) class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Calcium Channel Blockers (Non-DHP)	Cartia XT diltiazem diltiazem ER/CD Dilt-XR Taztia XT® Tiadylt ER® verapamil	*Calan® SR* *Cardizem®* *Cardizem CD®* *Cardizem LA®* *diltiazem ER (generic Cardizem LA®)* *Matzim LA™* *Tiazac ER®* *verapamil ER capsules, tablets* *verapamil ER PM* *Verelan®* *Verelan PM®*

Movement Disorders

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Movement Disorders* class, require PA until reviewed by the P&T Advisory Committee

Drug Class	Preferred Agents	Non-Preferred Agents
Movement Disorders	Austedo® CC, AE, QL Ingrezza® AE, QL tetrabenazine	*Ingrezza® Initiation pack AE, QL* *Xenazine®*

Pulmonary Arterial Hypertension (PAH) Agents

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Pulmonary Arterial Hypertension (PAH)* Agents class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Pulmonary Arterial Hypertension (PAH) Agents	Alyq® CC, QL ambrisentan CC sildenafil tablets CC tadalafil CC, QL	*Adcirca™ QL* *Adempas® QL* *bosentan tablets* *Letairis™*

Drug Class	Preferred Agents	Non-Preferred Agents
	Tracleer® tablets[CC, QL] *Revatio suspension™* [CC]	*Opsumit®* [QL] *Orenitram ER™* *Revatio tablets™* [CC] sildenafil suspension[CC] *Tracleer® 32 mg tablets for suspension*[CC, QL] *Tyvaso™* *Tyvaso™ DPI* *Uptravi®* [QL] *Ventavis®* [CC]

Classes Reviewed by Consent Agenda

No change in PDL status:

- Alzheimer's Agents
- Angiotensin Modulators (Angiotensin Receptor Blockers)
- Angiotensin Modulator Combinations
- Antianginal & Anti-Ischemic
- Antiarrhythmics, Oral
- Anticoagulants
- Anticonvulsants: Carbamazepine Derivatives
- Anticonvulsants: First Generation
- Antidepressants, Other
- Antidepressants, SNRI
- Antidepressants, SSRI
- Antiparkinson's Agents (Parkinson's Disease)
- Antipsychotics: First-Generation (oral)
- Antipsychotics: Second-Generation (oral)
- Anxiolytics
- Bladder Relaxant Preparations
- BPH Treatments
- Calcium Channel Blockers (DHP)
- Lipotropics, Other
- Lipotropics, Statins
- Platelet Aggregation Inhibitors
- Stimulants and Related Agents
- Tobacco Cessation Products