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 **November 17, 2016**, and the recommendations delivered by the P&T Committee members in attendance:

New Products to Market

Qbrelis™ – Non-prefer in PDL class: *Angiotensin Receptor Blockers* (*Angiotensin Modulators)*

Length of Authorization: 1 year

Qbrelis (lisinopril) oral solution is indicated for the treatment of hypertension in adults and pediatric patients equal to or greater than 6 years of age as adjunct therapy for systolic heart failure in adults, and for reduction of mortality in acute myocardial infarction (AMI) in adults.

Approval Criteria:

- 6 - 17 years of age; AND
- Have diagnosis of hypertension; AND
- Have eGFR > 30mL/min/1.73m^2; AND
- Not be able to take an oral capsule or tablet.

OR

- Patient must not be pregnant; AND
- ≥ 18 years of age; AND
- Have diagnosis of heart failure, acute myocardial infarction, or hypertension; AND
- Not be able to take an oral capsule or tablet.

Quantity Limit = adults: 40mg per day; pediatrics - 0.61mg per kg per day or 40mg per day, whichever is lower (to be determined during the clinical review of the PA request).

Class	Preferred	Non-Preferred
Angiotensin Receptor Blockers	losartan valsartan	*Atacand®* *Avapro®* *Benicar®* *candesartan* *Cozaar®* *Diovan®* *Edarbi™* *Entresto™ CC* *eprosartan* *irbesartan* *Micardis®* *Qbrelis™* *telmisartan* *Teveten®*

Byvalson™ – Non-prefer in the PDL class: *Angiotensin Modulator + Combinations (Angiotensin Modulator Combinations)*

Length of Authorization: 1 year

Byvalson (nebivolol/valsartan) is the combination of a beta-blocker and an angiotensin II receptor blocker (ARB) available as a 5mg/80mg tablet. It is indicated for the treatment of hypertension (HTN).

Approval Criteria:

Patient has had a trial and failure of 2 first-line HTN therapies comprised of multiple single agents used in combination (e.g., Calcium Channel Blocker [CCB] + Angiotensin Converting Enzyme Inhibitor [ACEI]).

Quantity Limit = 1 tablet per day

Class	Preferred	Non-Preferred
Angiotensin Modulator + Combinations	amlodipine/benazepril Exforge HCT® ST valsartan/amlodipine ST	*Azor™* *Byvalson™ QL* *Exforge®* *Lotrel®* *Prestalia® QL* *Tarka®* *Tribenzor®* *telmisartan/amlodipine* *Twynsta®* *valsartan/amlodipine/HCTZ* *verapamil/trandolapril*

Zurampic® – Non-prefer in PDL class: *Antihyperuricemics*

Length of Authorization: 1 year

Zurampic (lesinurad) 200mg tablets are indicated for use in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.

Approval Criteria:

- ≥ 18 years of age; AND
- Have symptomatic hyperuricemia associated with gout; AND
- Have documented trial and failure of xanthine oxidase inhibitor monotherapy at maximum tolerated dose; AND
- Using lesinurad in combination with a xanthine oxidase inhibitor; AND
- Patient does not have severe renal impairment (CrCl < 45mL/min), ESRD, kidney transplant, or is on dialysis; AND
- Patient does not have tumor lysis syndrome or Lesch-Nyhan syndrome.

Quantity Limit = 1 tablet per day

Class	Preferred	Non-Preferred
Antihyperuricemics	allopurinol probenecid probenecid/colchicine	*colchicine* CC *Colcrys®* CC *Mitigare®* CC *Uloric®* CC *Zurampic®* QL *Zyloprim®*

Relistor® (oral) – Non-prefer in PDL class: *GI Motility Agents (GI Motility, Chronic)*

Length of Authorization: 6 months

Relistor (methylnaltrexone bromide) tablets are indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

Approval Criteria:

- ≥18 years of age; AND
- Patient does not have known or suspected mechanical gastrointestinal obstruction; AND
- If patient is female, must not currently be breastfeeding; AND
- Response to standard laxative therapy is inadequate (<3 bowel movements in preceding 7 days).

Standard therapy is defined as routine, scheduled use of 3 or more of the following:

- Dietary changes
- Stool softeners
- Stimulant laxatives
- Osmotic or saline laxatives
- Bulk forming laxatives
- Lubricants

Quantity Limit = 3 tablets per day

Class	Preferred	Non-Preferred
GI Motility Agents	Amitiza® CC Linzess® CC	*alosetron* CC *Lotronex®* CC *Movantik®* *Relistor® tablets* QL *Viberzi®* QL

Epclusa® – Prefer in PDL class: *Hepatitis C Agents; (Hepatitis C Agents)*

Prefer for Genotypes 2 and 3 ONLY.

Length of Authorization: 12 weeks

Epclusa (sofosbuvir/velpatasvir) 400mg/100mg tablets is a fixed-dose combination of a nucleotide analog NS5B polymerase inhibitor (sofosbuvir) and an NS5A inhibitor (velpatasvir) indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection, with or without compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.

All class criteria must be met for approval.

Quantity Limit: 28 tablets per 28 days

Class	Preferred	Non-Preferred
Hepatitis C: Direct-Acting Antiviral Agents	Daklinza™ CC, QL	*Harvoni® CC, QL*
	Epclusa®	*Olysio™ CC, QL*
	Technivie™ CC, QL	*Sovaldi™ CC, QL*
	Viekira XR and Pak® CC, QL	*Zepatier™ CC, QL*

Otovel™ – Non-prefer in PDL class: *Otic Antibiotics*

Length of Authorization: 7 days

Otovel™ (ciprofloxacin/fluocinolone acetonide) solution, for otic use, is a combination of an antibacterial and a corticosteroid. Each single-dose vial contains ciprofloxacin 0.3% along with fluocinolone acetonide 0.025%. Otovel solution is indicated for the treatment of acute otitis media with tympanostomy tubes in pediatric patients aged 6 months and older due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis*, and *Pseudomonas aeruginosa,* for a duration of no more than 7 days.

Approval Criteria:

- Patient ≥ 6 months of age; AND
- Diagnosis of acute otitis media; AND
- Patient has tympanostomy tubes; AND
- Patient does not have a viral infection of the external ear canal or any fungal otic infection.

Class	Preferred	Non-Preferred
Otic Antibiotics	CiproDex® Otic	*Cetraxal®*
	ciprofloxacin 0.2%	*Cipro HC® Otic*
	hydrocortisone 1%/neomycin sulfate 5 mg/polymyxin B 10,000 units solution, suspension	*Coly-mycin® S*
		Cortisporin® solution
		Cortisporin® – TC
		ofloxacin 0.3% solution
		Otovel™

Class Review and Criteria Reviews

Antipsychotics; First Generation, Second Generation, Injectables, and Combination Products

First Generation:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities, at least 1 representing an agent from each of the potency groups, should be preferred.
- Agents not selected as preferred will be considered non-preferred and require prior authorization.
- Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back.
- For any new chemical entity in the *First Generation Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee.

Second Generation:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 5 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require prior approval.
- Continue quantity limits on agents in this class.
- Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back.
- For any new chemical entity in the *Second-Generation Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee.

Injectables:

- DMS to select preferred agent(s) based on economic evaluation. Generic formulations of first generation injectable antipsychotics should be preferred. Additionally, 2 unique second generation injectable antipsychotics, 1 of which should have a duration of action of 2 weeks or longer, should be preferred.
- Agents not selected as preferred will be considered non-preferred and require prior approval.
- Continue quantity limits on agents in this class.
- Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back.
- For any new chemical entity in the *Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee.

Combination Products:

- DMS to select preferred agent(s) based on economic evaluation.
- Agents not selected as preferred will be considered non-preferred and require prior approval.
- Continue quantity limits on agents in this class.
- Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back.
- For any new chemical entity in the *Second Generation Antipsychotic* and *SSRI Combination* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
First-Generation Antipsychotics	amitriptyline/perphenazine chlorpromazine fluphenazine haloperidol loxapine Orap® perphenazine thioridazine thiothixene trifluoperazine	*Adasuve®* *pimozide*

Class	Preferred	Non-Preferred
Second-Generation Antipsychotics	aripiprazole tablets CC, QL clozapine CC, QL clozapine ODT CC, QL Fanapt™ CC, QL Latuda® CC, QL olanzapine CC, QL quetiapine CC, QL risperidone CC, QL Saphris® CC, QL Seroquel® XR CC, QL ziprasidone CC, QL	*Abilify® oral formulations CC, QL* *aripiprazole ODT, solution CC, QL* *Clozaril® QL* *FazaClo® QL* *Geodon® QL* *Invega® QL* *Nuplazid™ QL* *paliperidone QL* *Rexulti® QL* *Risperdal® QL* *Seroquel® QL* *Versacloz® QL* *Vraylar™ QL* *Zyprexa® QL*

Note: Grandfathering is permitted for those utilizing aripiprazole ODT or solution formulations prior to the effective date of the November 2016 PDL changes provider notice.

Class	Preferred	Non-Preferred
Antipsychotics: Injectable	Abilify Maintena™ CC, QL fluphenazine decanoate CC, QL Geodon® CC, QL haloperidol decanoate CC, QL haloperidol lactate CC, QL Invega® Sustenna® CC, QL *Invega Trinza™ QL* olanzapine CC, QL Risperdal® Consta® CC, QL	*Aristada™* *Haldol® Decanoate QL* *Haldol® lactate QL* *Zyprexa® QL* *Zyprexa® Relprevv QL*

Class	Preferred	Non-Preferred
Atypical Antipsychotic and SSRI Comb.	Symbyax® CC, QL	*olanzapine/fluoxetine QL*

Oncology Oral; Other

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred.
- Continue quantity limits based on FDA-approved maximum dose.
- Agents not selected as preferred will be considered non-preferred and require PA.
- DMS to allow continuation of therapy for existing users of non-preferred, single-source branded products via a 90-day look back.
- For any new chemical entity in the *Oral Oncology, Other* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Oral Oncology, Other	Cometriq™ QL temozolomide Xeloda®	*capecitabine* *Caprelsa® QL* *Lonsurf®* *Lynparza™ QL* *Stivarga® CC, QL* *Temodar®*

Ophthalmic; Antihistamines and Mast-Cell Stabilizers

Antihistamines:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Antihistamines* class, require a PA until reviewed by the P&T Advisory Committee.

Mast-Cell Stabilizers:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Mast Cell Stabilizers* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Ophthalmic Antihistamines	Pataday™ Pazeo™	*azelastine* *Bepreve™* *Elestat™* *Emadine®* *epinastine* *Lastacaft™* *Optivar®* *Patanol®*

Class	Preferred	Non-Preferred
Ophthalmic Mast Cell Stabilizers	cromolyn sodium	*Alocril®* *Alomide®*

Ophthalmic; Antibiotic-Steroid Combinations

- 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 *Ophthalmic Antibiotics-Steroid Combinations* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Ophthalmic Antibiotic-Steroid Combinations	Blephamide® dexamethasone/neomycin sulfate/polymyxin B sulfate hydrocortisone/bacitracin zinc/neomycin sulfate/polymyxin B sulfates Tobradex®	*Blephamide® S.O.P.* *dexamethasone/tobramycin* *hydrocortisone/neomycin sulfate/polymyxin B sulfate* *Maxitrol®* *Pred-G®* *Pred-G® S.O.P.* *prednisolone sodium phosphate / sulfacetamide sodium* *Tobradex® ST* *Zylet™*

Ophthalmic; NSAIDs and Anti-Inflammatory Steroids

NSAIDs:

- 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 *Ophthalmic NSAIDs* class, require a PA until reviewed by the P&T Advisory Committee.

Anti-Inflammatory Steroids:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 3 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 *Ophthalmic Anti-inflammatory Steroids* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Ophthalmic NSAIDs	diclofenac flurbiprofen ketorolac	*Acular®* *Acular LS®* *Acuvail®* *bromfenac* *Ilevro™* *Nevanac™* *Ocufen®* *Prolensa™* *Voltaren®*

Class	Preferred	Non-Preferred
Ophthalmic Anti-Inflammatory Steroids	dexamethasone sodium phosphate Durezol™ fluorometholone prednisolone acetate prednisolone sodium phosphate	*Alrex®* *Flarex®* *FML®* *FML Forte®* *FML S.O.P.®* Lotemax™ Maxidex® *Omnipred™* *Ozurdex™* *Pred Forte®* *Pred Mild®* *Retisert™* *Triesence®* *Vexol®*

Ophthalmic; Immunomodulators

New Product to class: Xiidra™ – Non-prefer

Length of Authorization: 6 months initial; 1 year re-approval

Xiidra (lifitegrast) 5% ophthalmic solution is a lymphocyte function-associated antigen-1 (LFA-1) antagonist approved for treating the signs and symptoms of dry eye disease in adults.

Initial Criteria Approval:

- ≥ 17 years of age; AND
- Have a diagnosis of chronic dry eye disease (DED) (e.g., not associated with seasonal allergies) or chronic eye dryness secondary to Sjögren's syndrome; AND
- Have presence of conjunctival redness; AND
- Have 1 of the following:
  - Corneal fluorescein staining score of ≥ 2 points in any field on a 0 to 4 point scale; OR
  - Schirmer tear test (STT) of 1 to 10 mm in 5 minutes; AND
- NOT be using concurrent ophthalmic cyclosporine (Restasis); AND
- Have had an adequate trial and failure of over-the-counter (OTC) artificial tears (use of at least 4 times daily).

Renewal Criteria:

Patient must:

- Have improvement in signs of DED as measured by at least 1 of the following:
  - Decrease in corneal fluorescein staining score; OR
  - Increase in number of mm per 5 minutes using Schirmer tear test; AND
- Decrease in conjunctival redness; AND
- Have improvement in ocular discomfort; AND
- NOT be using concurrent ophthalmic cyclosporine (Restasis); AND
- Not be using supplemental artificial tears concurrently with lifitegrast (Xiidra).

Quantity Limit: 60 single-use containers per 30 days.

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Immunomodulator* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Ophthalmic Immunomodulator	Restasis® ST	*Xiidra™ QL*

Ophthalmic; Beta-Blockers, Carbonic Anhydrase Inhibitors, Combinations, Direct-Acting Miotics, Prostaglandin Agonists, and Sympathomimetics

Beta-blockers:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Glaucoma, Beta-blockers* class, require a PA until reviewed by the P&T Advisory Committee.

Carbonic Anhydrase Inhibitors:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Glaucoma, Carbonic Anhydrase Inhibitors* class, require a PA until reviewed by the P&T Advisory Committee.

Combinations:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 combination product containing an ophthalmic beta-agonist should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Combinations for Glaucoma* class, require a PA until reviewed by the P&T Advisory Committee.

Direct-Acting Miotics:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Glaucoma Direct-Acting Miotics* class, require a PA until reviewed by the P&T Advisory Committee.

Prostaglandin Agonists:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- Continue current quantity limits on agents in this class.
- For any new chemical entity in the *Ophthalmic Glaucoma, Prostaglandin Analogs* class, require a PA until reviewed by the P&T Advisory Committee.

Sympathomimetics:

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Ophthalmic Sympathomimetics* class, require a PA until reviewed by the P&T Advisory Committee.

Class	Preferred	Non-Preferred
Ophthalmic Beta Blockers	levobunolol timolol maleate	*Betagan®* *betaxolol* *Betimol®* *Betoptic S®* *carteolol* *Istalol®* *metipranolol* *Optipranolol®* *Timoptic®* *Timoptic XE®*

Class	Preferred	Non-Preferred
Ophthalmic Carbonic Anhydrase Inhibitors	Azopt® dorzolamide	*Trusopt®*

Class	Preferred	Non-Preferred
Ophthalmic Combinations for Glaucoma	Combigan™ dorzolamide/timolol Simbrinza™	*Cosopt®* *Cosopt PF®*

Class	Preferred	Non-Preferred
Ophthalmic Glaucoma Direct Acting Miotics	N/A	*Isopto Carpine®* *pilocarpine* *Pilopine HS® 4%*

Class	Preferred	Non-Preferred
Ophthalmic Prostaglandin Agonists	latanoprost QL	*bimatoprost QL* *Lumigan® QL* *Rescula® QL* *Travatan Z® QL* *travoprost QL* *Xalatan® QL* *Zioptan® QL*

Class	Preferred	Non-Preferred
Ophthalmic Sympathomimetics	Alphagan P® 0.15% brimonidine 0.2%	*Alphagan P® 0.1%* *apraclonidine* *brimonidine 0.15%* *Iopidine®*

Consent Agenda

By Department approval, the PDL status for the following therapeutic classes remains unchanged.

- Antianginal & Anti-ischemic Agents
- Antiarrhythmics, Oral
- Antibiotics, Topical
- Anticoagulants
- Antiemetic & Antivertigo Agents
- BPH Agents
- Bronchodilators, Beta-Agonists
- Calcium Channel Blockers
- Cytokine & CAM Antagonists
- H. Pylori Agents
- Hepatitis C Agents (Interferons & Ribavirins)
- Laxatives & Cathartics
- Lipotropics, Other
- Neuropathic Pain
- Oncology Oral – Hematologic
- Ophthalmics, Antibiotics
- Ophthalmics, Antivirals
- Ophthalmics, Mydriatics
- Platelet Aggregation Inhibitors
- Proton Pump Inhibitors
- Stimulants & Related Agents
- Thrombopoiesis Stimulating Proteins