

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, 2022**, and the resulting official recommendations.

New Products to Market

Ztalmy®

Non-prefer in the PDL class: *Anticonvulsants: Second Generation*

Length of Authorization: 1 year

- Ganaxolone (Ztalmy) is a neuroactive steroid gamma-aminobutyric acid (GABA). A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients ≥ 2 years of age.

Criteria for Approval:

Initial Approval Criteria

- Patient is ≥ 2 years of age; AND
- Patient has a diagnosis of seizures associated with cyclin dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing; AND
- Patient has tried ≥ 2 other anticonvulsant medications; AND
- Patient will avoid concomitant therapy with moderate or strong CYP450 inducers (e.g., carbamazepine, phenobarbital, phenytoin, omeprazole), or if concomitant therapy is unavoidable, dose adjustments will be considered; AND
- Ganaxolone is prescribed by or in consultation with a neurologist.

Renewal Criteria

- Patient must continue to meet the above criteria; AND
- Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline; AND
- Patient has not experienced any treatment-restricting adverse effects (e.g., somnolence, pyrexia, suicidal thoughts or behavior)

Quantity Limit: 1800mg (36mL) per day

Age Limit: 2 years of age

Drug Class	Preferred Agents	Non-Preferred Agents
Anticonvulsants: Second Generation	Banzel® CC, QL Gabitril® QL lacosamide solution, tablets QL lamotrigine chewable tablets, tablets (except dose packs) levetiracetam ER QL levetiracetam solution, tablets QL Sabril® CC, QL topiramate QL zonisamide QL	Briviact® CC, QL Diacomit™ CC, QL Elepsia® XR QL Epidiolex™ CC 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 QL Vimpat® QL Xcopri® CC, QL Zonisade™ QL Ztalmly® AE, CC, QL

Zoryve®

Non-prefer in the PDL class: *Topical Psoriasis Agents*

Length of Authorization: 1 year

- Phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas (e.g., groin folds, axillae, gluteal cleft), in patients ≥ 12 years old.

Criteria for Approval:

Initial Approval Criteria

- Patient must have an adequate trial and failure, contraindication or intolerance, of at least two preferred medications within the last 90 days.

Age Limit: ≥ 12 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™

Drug Class	Preferred Agents	Non-Preferred Agents
		<i>Enstilar</i> [®] MD, AE <i>Kerafoam</i> [™] <i>Salex</i> [™] <i>Sorilux</i> [™] <i>Taclonex</i> [®] <i>Uramaxin</i> [®] <i>Uramaxin</i> [®] GT <i>Vectical</i> [™] <i>Vtama</i> [®] AE, QL <i>Zoryve</i> [®] AE, QL

Vivjoa[®]

Non-preferred in the PDL class: *Antifungals, Oral*

Length of Authorization: 1 year

- Oteseconazole (Vivjoa) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

Criteria for Approval:

Initial Approval Criteria

- Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period; AND
- Patient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); AND
- Patient must not have hypersensitivity to any component of the product; AND
- Patient is not pregnant; AND
- Patient is not lactating; AND
- Patient has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole x 6 months

Age Limit: none

Quantity Limit: 18 tablets per treatment course

Drug Class	Preferred Agents	Non-Preferred Agents
Antifungals, Oral	clotrimazole fluconazole griseofulvin suspension itraconazole capsules CC, QL nystatin suspension, tablets terbinafine	<i>Ancobon</i> [®] <i>Brexafemme</i> [®] <i>Cresemba</i> [®] <i>Diflucan</i> [®] <i>flucytosine</i> <i>griseofulvin microsize tablets</i> <i>griseofulvin ultramicrosize</i> <i>itraconazole solution</i>

Drug Class	Preferred Agents	Non-Preferred Agents
		<i>ketoconazole</i> <i>Noxafil®</i> <i>Oravig™</i> <i>posaconazole</i> <i>Sporanox®</i> <i>Tolsura</i> <i>Vfend®</i> <i>Vivjoa® CC, QL</i> <i>voriconazole</i>

Sotyktu®

Non-preferred in the PDL class: *Cytokine and CAM Antagonists*

Length of Authorization: 1 year

- Deucravacitinib (Sotyktu) is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is not recommended for use in combination with other potent immunosuppressants.

Criteria for Approval:

- Diagnosis of moderate to severe plaque psoriasis; AND
- Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; AND
- Symptoms persistent for ≥ 6 months with at least 1 of the following:
 - Involvement of at least 3% of body surface area (BSA); OR
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
 - Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); AND
- Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
 - Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate
 - Immunosuppressant (e.g., cyclosporine)
 - Oral retinoid (e.g., acitretin); AND
- NOT used in combination with any other biologic agent; AND
- Trial and failure (at least 3 months) unless contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; AND
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.

Age Limit: ≥ 18 years

Quantity Limit: 1 per day

Drug Class	Preferred Agents	Non-Preferred Agents
Cytokine and CAM Antagonists	<p>Cosentyx® CC, QL</p> <p>Enbrel® CC, QL</p> <p>Humira® CC, QL</p> <p>Otezla® CC, QL</p>	<p>Actemra® CC, QL</p> <p>Cibinqo™ CC, QL</p> <p>Cimzia® CC, QL</p> <p>Enspryng™ CC, AE, QL</p> <p>Ilumya™ CC, AE, QL</p> <p>Kevzara® CC, AE, QL</p> <p>Kineret® CC, QL</p> <p>Olumiant® CC, AE, QL</p> <p>Orencia® CC, QL</p> <p>Rinvoq™ CC, AE, QL</p> <p>Siliq™ CC, AE, QL</p> <p>Simponi™ CC, QL</p> <p>Skyrizi™ CC, AE, QL</p> <p>Sotyktu® AE, CC, QL</p> <p>Stelara™ CC, QL</p> <p>Taltz® CC, QL</p> <p>Tremfya™ CC, AE, QL</p> <p>Xeljanz® CC, QL</p> <p>Xeljanz® XR CC, QL</p>

Existing Product to be reviewed as a Single Product

Tyvaso® Tyvaso DPI™

Non-preferred in the PDL class: *Pulmonary Arterial Hypertension (PAH) Agents*

Length of Authorization: 1 year

- Treprostinil (Tyvaso® Tyvaso DPI™) is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.

Criteria for Approval:

Pulmonary Arterial Hypertension (PAH)

- Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1
- Prescribed by, or in consultation with, a cardiologist or a pulmonologist
- Patient has trial and therapeutic failure, allergy, contraindication or intolerance to 2 or more preferred agents for at least 1 month.

Pulmonary Hypertension Associated with Interstitial Lung Disease

- Diagnosis of Pulmonary Hypertension Associated with Interstitial Lung Disease WHO Group 3
- Prescribed by, or in consultation with, a cardiologist or a pulmonologist
- Baseline forced vital capacity < 70% for patients with connective tissue disease
- Patient has had a right heart catheterization (documentation required)

- Results of the right heart catheterization confirm the diagnosis of WHO Group 3 interstitial lung disease associated with pulmonary hypertension

Renewal Criteria

- Patient has a documented response to therapy
- Patient has not experienced any treatment limiting adverse effects

Drug Class	Preferred Agents	Non-Preferred Agents
Pulmonary Arterial Hypertension (PAH)	Alyq® CC, QL ambrisentan CC Revatio suspension™ CC sildenafil tablets CC tadalafil CC, QL Tracleer® tablets CC, QL	Adcirca™ QL Adempas® QL bosentan tablets Letairis™ Opsumit® QL Orenitram ER™ Revatio tablets™ CC sildenafil suspension CC Tracleer® 32 mg tablets for suspension CC, QL Tyvaso™ CC Tyvaso DPI™ CC Upravi® QL Ventavis® CC

Full Class Reviews

Anticonvulsants: First Generation

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 *Anticonvulsants: First Generation* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Anticonvulsants: First Generation	Celontin® clobazam QL clonazepam tablets QL diazepam rectal gel QL divalproex delayed-release divalproex sodium ER divalproex sprinkle ethosuximide	clonazepam ODT Depakene® Depakote® Depakote ER® Depakote® Sprinkle Diastat® QL Dilantin® Felbatol®

Drug Class	Preferred Agents	Non-Preferred Agents
	felbamate Nayzilam® QL Peganone® phenobarbital CC phenytoin IR/ER primidone CC valproate valproic acid Valtoco® QL	Klonopin® QL Mysoline® Onfi™ QL Phenytek® Sympazan™ CC, QL Zarontin®

Topical Antifungal Agents

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least one 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 *Topical Antifungals Agents* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Antifungal Agents	ciclopirox cream, solution clotrimazole cream, solution clotrimazole/betamethasone cream ketoconazole cream QL ketoconazole shampoo Nyamyc® nystatin cream, ointment, powder QL nystatin/triamcinolone cream, ointment Nystop®	Ciclodan® cream, kit, solution ciclopirox suspension, shampoo, gel, kit clotrimazole/betamethasone lotion econazole Ertaczo® Exelderm® Extina® Jublia® CC Kerydin™ CC ketoconazole foam Ketodan™ Loprox® luliconazole Luzu® Mentax® miconazole/zinc oxide/petrolatum naftifine Naftin® Oxiconazole QL Oxistat® QL sulconazole nitrate cream, solution tavaborole

Drug Class	Preferred Agents	Non-Preferred Agents
		<i>Triamazole™ CC, QL</i> <i>Vusion®</i>

Anti-Emetics: Other

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 will require PA.
- For any new chemical entity in the *Anti-Emetics: Other* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Anti-Emetics: Other	Bonjesta® meclizine metoclopramide oral solution, tablets prochlorperazine tablets promethazine syrup, tablets promethazine/Promethegan 12.5, 25 mg suppositories scopolamine patches	<i>Antivert®</i> <i>Bonjesta® CC</i> <i>Compro®</i> <i>Diclegis™ CC, QL</i> <i>doxylamine/pyridoxine CC, QL</i> <i>Gimoti™ CC, QL</i> <i>metoclopramide ODT</i> <i>prochlorperazine suppositories</i> <i>promethazine/Promethegan 50 mg suppositories</i> <i>Reglan®</i> <i>Transderm-Scop®</i> <i>trimethobenzamide</i>

Topical Antiviral Agents

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least one 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 *Topical Antiviral Agents* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Antiviral Agents	acyclovir cream , ointment	<i>Denavir®</i> <i>Xerese™</i> Zovirax® cream , ointment

Drug Class	Preferred Agents	Non-Preferred Agents

GI Motility Agents

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 *GI Motility Agents* class, require PA until reviewed by the P&T Advisory Committee.

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

Immunomodulators, Atopic Dermatitis

Class Selection & Guidelines

- 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 *Immunomodulators, Atopic Dermatitis* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Immunomodulators, Atopic Dermatitis	Dupixent® CC, QL Elidel® Eucrisa® CC, QL Protopic®	<i>Adbry</i> ™ CC, AE, QL <i>Opzelura</i> ™ CC, AE <i>pimecrolimus</i> <i>tacrolimus ointment</i>

Multiple Sclerosis Agents

Class Selection & Guidelines

- 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 will require PA.
- For any new chemical entity in the *Multiple Sclerosis Agents* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Multiple Sclerosis Agents	Avonex® CC, QL Betaseron® CC, QL Copaxone® 20 mg CC, QL dalfampridine ER QL dimethyl fumarate CC, QL Gilenya™ CC, QL Rebif® CC, QL	Ampyra™ QL Aubagio® QL Bafiertam™ AE, QL Copaxone® 40 mg QL Extavia® QL fingolimod QL glatiramer acetate QL Glatopa™ QL Kesimpta® CC, AE, QL Mavenclad® CC, AE, QL Mayzent® CC, AE, QL Plegridy® QL Ponvory™ CC, AE, QL Tascenso ODT™ Tecfidera™ QL Vumerity™ AE, QL Zeposia® CC, AE, QL

Topical Steroids

Class Selection & Guidelines

- DMS to select preferred agent (s) based on economic evaluation; however, at least two agents in each of the potency categories (low, medium, high, and very high) should be preferred.
- Agents not selected as preferred will be considered non preferred and require PA.
- For any new chemical entity in the *Topical Steroids* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Topical Steroids	alclometasone dipropionate Anusol® HC betamethasone dipropionate cream, lotion betamethasone dipropionate (augmented) cream betamethasone valerate cream, ointment clobetasol propionate cream, ointment,	amcinonide Ana-Lex™ Aqua Glycolic HC® Beser™ betamethasone dipropionate ointment betamethasone dipropionate augmented

Drug Class	Preferred Agents	Non-Preferred Agents
	shampoo, solution Clodan® shampoo Derma-Smoothe/FS® desonide cream, ointment fluocinonide ointment, solution fluticasone propionate cream, ointment halobetasol propionate cream, ointment hydrocortisone cream, lotion, ointment mometasone furoate cream, ointment, solution Procto-Med HC™ Procto-Pak™ Proctosol-HC® Proctozone-HC™ triamcinolone acetonide cream, lotion, ointment	ointment, lotion, gel betamethasone valerate foam, lotion Bryhali™ Capex® Shampoo clobetasol emollient clobetasol propionate foam, gel, lotion, spray Clobex® clocortolone Clodan® kit Cloderm® desonide lotion desoximetasone diflorasone diacetate Diprolene® fluocinolone acetonide oil, cream, ointment, solution fluocinonide emollient fluocinonide cream, gel flurandrenolide fluticasone propionate lotion halcinonide cream halobetasol propionate foam Halog® hydrocortisone butyrate hydrocortisone butyrate/emollient hydrocortisone valerate cream, ointment Impeklo™ Kenalog® Lexette Lidocort™ Locoid® Locoid Lipocream® Luxiq® Olux®, Olux-E® Pandel® prednicarbate Proctocort® Sanaderm™ Rx Synalar®, Synalar® TS Temovate® Texacort® Topicort® Tivet™

Drug Class	Preferred Agents	Non-Preferred Agents
		<i>triamcinolone acetonide spray</i> <i>Ultravate®</i> <i>Vanos™</i>

Classes Reviewed by Consent Agenda

No change in PDL status:

- Acne Agents, Oral
- Acne Agents, Topical
- Antibiotics, Topical
- Anticholinergics/Antispasmodics
- Antidiarrheals
- Antiemetics & Antivertigo Agents
 - Oral Anti-Emetics: 5-HT3 Antagonists
 - Oral Anti-Emetics: NK-1 Antagonists
 - Oral Anti-Emetics: Δ-9-THC Derivatives
- Antiparasitic, Topical
- Antipsoriatic, Oral
- Antipsoriatics, Topical
- Anti-Ulcer Protectants
- Bile Salts
- Cytokine and CAM Antagonists
- Histamine II Receptor Blockers
(H2 Receptor Antagonists)
- *H. pylori* Treatment
- Immunomodulators, Asthma
- Immunosuppressives, Oral (Immunosuppressants)
- Laxatives and Cathartics
- Ophthalmics, Allergic Conjunctivitis
 - Ophthalmic Antihistamines
 - Ophthalmic Mast Cells Stabilizers
- Ophthalmics, Antibiotics
 - Ophthalmic Quinolones
 - Ophthalmic Antibiotics, Non-Quinolones
- Ophthalmics, Antibiotics-Steroid Combinations
- Ophthalmics, Anti-inflammatories
 - Ophthalmic NSAIDs
 - Ophthalmic Anti-inflammatory Steroids
- Ophthalmics, Antivirals
- Ophthalmics, Glaucoma Agents
 - Ophthalmic Beta Blockers
 - Ophthalmic Carbonic Anhydrase Inhibitors
 - Ophthalmic Combinations for Glaucoma

- Ophthalmic Prostaglandin Agonists
- Ophthalmic Sympathomimetics
- Ophthalmic Glaucoma Agents, Other
- Ophthalmic Immunomodulators
- Ophthalmics, Mydriatics & Mydriatic Combinations
- Ophthalmic Vasoconstrictors
- Otic Antibiotics
- Otic Anesthetic and Anti-Inflammatories
- Proton Pump Inhibitors
- Rosacea Agents, Topical
- Spinal Muscular Atrophy
- Ulcerative Colitis Agents