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 20, 2018**, and the recommendations delivered by the P&T Committee members in attendance.

New Products to Market

Aimovig™– Non-prefer in the PDL class: *Antimigraine, Other (Antimigraine: CGRP Inhibitors)*
Length of Authorization: 3 months initial; 1 year renewal

Aimovig (erenumab-aooe), a monoclonal antibody that targets the calcitonin gene-related peptide (CGRP) receptor, is indicated for the preventative treatment of migraine in adults. It is available as a 70 mg/mL solution in a single-dose prefilled syringe or auto-injector for monthly subcutaneous administration of 70 or 140 mg as one or two injections, respectively.

Criteria for Approval:

- Diagnosis of migraine with or without aura; AND
- If female of child-bearing age (18-45), negative pregnancy screening; AND
- Trial and failure (≥ 1 month) of **at least 2** medications – at least 1 must be level A or B recommendation – listed below from the 2012 American Academy of Neurology/American Headache Society guidelines:

Level A	Level B	Level C	
AEDs: -divalproex sodium -sodium valproate -topiramate	*Antidepressants:* -amitriptyline -venlafaxine	*Alpha-agonists:* -clonidine -guanfacine	*ACE/ARB:* -lisinopril -candesartan
Beta blockers: -metoprolol -propranolol -timolol	*Beta blockers:* -atenolol -nadolol	*AEDs:* -carbamazepine	*Beta blockers:* -nebivolol -pindolol
	NSAIDs: -fenoprofen -ibuprofen -ketoprofen -naproxen	*Antihistamines:* -cyproheptadine	*NSAIDs:* -flurbiprofen -mefenamic acid

AED = antiepileptic drug; ACE = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; NSAID = nonsteroidal anti-inflammatory drug

Renewal Criteria

- Patient has an overall improvement in function with therapy; AND
- If female of child-bearing age, continued monitoring for pregnancy.

Age Limit: ≥ 18 years
Quantity Limit: 1 package (70 or 140 mg) per month

Drug Class	Preferred Agents	Non-Preferred Agents
Antimigraine: CGRP Inhibitors	N/A	*Aimovig™ CC, QL*

Olumiant®– Non-prefer in the PDL class: *Cytokine and CAM Antagonists (Immunomodulators)*
Length of Authorization: 1 year

Olumiant® (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. It is available as a 2 mg tablet for oral administration.

Criteria for Approval:

- Diagnosis of moderately to severely active rheumatoid arthritis (RA); AND
- Trial and failure (at least 3 months) of at least 1 oral disease-modifying antirheumatic drug (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, leflunomide, etc.; AND
- Trial and failure of (at least 3 months), or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®).
- Negative tuberculosis (TB) screening prior to initiating treatment; AND
- Olumiant® will not be used with a TNFα inhibitor (e.g., Enbrel®, Humira®) or other biologic DMARD (e.g., Actemra®, Orencia®)

Renewal Criteria:

- Meet initial approval criteria; AND
- Ongoing monitoring for TB; AND
- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts.

Age Limit: ≥ 18 years
Quantity Limit: 1 tablet per day

Drug Class	Preferred Agents	Non-Preferred Agents
Immunomodulators	Enbrel® CC QL Humira® CC, QL	*Actemra® CC, QL* *Cimzia® CC, QL* *Cosentyx® CC, QL* *Entyvio™ CC, QL* *Kevzara® CC, QL* *Kineret® CC, QL* *Olumiant® CC, QL* *Orencia® CC, QL* *Otezla® CC, QL* *Siliq™ CC, QL* *Simponi™ CC, QL* *Stelara™ CC, QL* *Taltz® CC, QL* *Tremfya™ CC, QL* *Xeljanz® CC, QL* *Xeljanz® XR CC, QL*

Rhopressa™– Non-prefer in the PDL class: *Ophthalmics, Glaucoma Agents (Other)*

Length of Authorization: 1 year

Rhopressa™ (netarsudil) is indicated to reduce intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG). It is a Rho kinase (ROCK) inhibitor theorized to reduce IOP through the trabecular mesh network; however, the exact mechanism is unknown.

Criteria for Approval:

- Have a diagnosis of ocular hypertension or open-angle glaucoma AND
- Have had at least a 1-month trial and failure of a prostaglandin inhibitor and/or beta-adrenergic antagonist.

Age Limit: ≥ 18 years

Quantity Limit: 5 mL per 30 days

Drug Class	Preferred Agents	Non-Preferred Agents
Ophthalmic Beta Blockers	levobunolol timolol maleate	*Betagan®* *betaxolol* *Betoptic S®* *carteolol* *Istalol®* *timolol maleate once daily (generic Istalol®)* *Timoptic®* *Timoptic XE®*
Ophthalmic Carbonic Anhydrase Inhibitors	Azopt® dorzolamide	*Trusopt®*
Ophthalmic Combinations for Glaucoma	Combigan™ dorzolamide/timolol Simbrinza™	*Cosopt®* *Cosopt PF®*
Ophthalmic Prostaglandin Agonists	latanoprost QL	*bimatoprost QL* *Lumigan® QL* *Travatan Z®* *Vyzulta™ CC, QL* *Xalatan® QL* *Zioptan® QL*
Ophthalmic Sympathomimetics	Alphagan P® 0.15% brimonidine 0.2%	*Alphagan P® 0.1%* *apraclonidine* *brimonidine 0.15%* *Iopidine®*
Ophthalmics, Glaucoma Agents (Other)	N/A	*Rhopressa CC, QL*

Tavalisse™– Non-prefer in the PDL class: *Thrombopoiesis Stimulating Agents*
Length of Authorization: 3 months initial; 1 year renewal

Tavalisse (fostamatinib) is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. It is available in 100 and 150 mg tablets for oral administration.

Criteria for Approval:

- Diagnosis of chronic immune thrombocytopenia (ITP); AND
- Trial and failure (e.g., not achieved a platelet count ≥ 50 x 10^9/L) of at least 1 other therapy for chronic ITP such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc.

Renewal Criteria:

- Laboratory values documenting platelet response to therapy (platelet count ≥ 50 x 10^9/L).

Age Limit: ≥ 18 years
Quantity Limit: 2 tablets per day

Drug Class	Preferred Agents	Non-Preferred Agents
Thrombopoiesis Stimulating Agents	Promacta® CC	*Nplate™ CC* *Tavalisse™ CC, QL*

Criteria Review

Compound Claims

Recommended Criteria: Claims for compounded medications ("compounds") that exceed $100 will now be subject to prior authorization (PA). Currently, compound claims will deny due to high cost at $5,000.

Exceptions: The POS system will bypass the PA for claims where the route of administration (ROA) is indicated as intravenous (IV) or intramuscular (IM) AND at least one medication billed is an antibiotic or other anti-infective agent.

Length of Authorization: 1 year
Criteria for Approval (ALL of the following conditions MUST be met):

- The compound contains ≥ 1 covered prescription ("Rx") required ingredient; AND
- ALL active ingredients in the compound product are FDA-approved, or are supported by peer-reviewed, medical literature and/or CMS-approved compendia (e.g., Micromedex) for the diagnosis in the requested route of delivery; AND
- If any ingredient in the compounded product requires PA, the member must meet the PA criteria for that ingredient; AND
- The member's drug therapy needs are unable to be met by commercially available dosage strengths and/or forms of the drug, as indicated by one of the following:
  - The FDA-approved or evidence-based dosage required for the patient's age or weight cannot be achieved with a commercially available product; OR

- Member has documented dysphagia and/or requires use of a feeding tube and there are no suitable commercially available products within the drug class; OR
- Member has a documented sensitivity to dyes, preservatives, or fillers in commercial products and requires a specialized preparation; OR
- There is a current supply shortage of the commercial product; OR
- The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness.

Full Class Reviews

Anticonvulsants

Class Selection & Guidelines

Anticonvulsants: First Generation

- DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities, including generic forms of clonazepam, divalproex, ethosuximide, phenobarbital, phenytoin, and valproate/valproic acid 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.

Anticonvulsants: Second Generation

- 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.

Anticonvulsants: Carbamazepine Derivatives

- 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 *Anticonvulsants: Carbamazepine Derivatives* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Anticonvulsants: First Generation	Celontin® clonazepam tablets QL DiaStat® QL divalproex DR divalproex sprinkle ethosuximide felbamate Peganone® phenobarbital CC Phenytek® phenytoin phenytoin ER primidone CC valproate/valproic acid	*clonazepam ODT* *Depakene®* *Depakote®* *Depakote ER®* *Depakote® Sprinkle* *diazepam rectal gel QL* *Dilantin®* *divalproex ER* *Felbatol®* *Klonopin® QL* *Mysoline®* *Onfi™ CC, QL* *Zarontin®*
Anticonvulsants: Second Generation	Banzel® CC, QL Gabitril® QL lamotrigine chewable tablets, tablets (except dose packs) levetiracetam solution, tablets QL Sabril® CC topiramate QL zonisamide QL	*Briviact® QL* *Fycompa™ QL* *Keppra® tablets QL, solution* *Keppra XR® QL* *Lamictal®* *Lamictal ODT®* *Lamictal® XR™ QL* *lamotrigine dose packs, ODT* *lamotrigine ER QL* *levetiracetam ER QL* *Qudexy® XR QL* *Spritam QL* *tiagabine QL* *Topamax® QL* *topiramate ER QL* *Trokendi XR™ QL* *vigabatrin* *Vimpat® QL* *Zonegran® QL*
Anticonvulsants: Carbamazepine Derivatives	carbamazepine chewable, tablets carbamazepine ER capsules (generic Carbatrol®) Equetro™ oxcarbazepine QL Tegretol® suspension Tegretol® XR	*Aptiom® QL* *carbamazepine ER tablets* *carbamazepine suspension* *Carbatrol®* *Oxtellar™ XR QL* *Tegretol® tablets* *Trileptal® QL*

Antiparkinson's Agents

Class Selection & Guidelines

Dopamine Receptor Agonists

- 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 will require PA.
- For any new chemical entity in the *Dopamine Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee.

Parkinson's Disease

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

Drug Class	Preferred Agents	Non-Preferred Agents
Dopamine Receptor Agonists	bromocriptine pramipexole ropinirole	*Mirapex®* *Mirapex® ER* *Neupro®* *Parlodel®* *pramipexole ER* *Requip®* *Requip® XL* *ropinirole ER*
Parkinson's Disease	amantadine capsules, syrup benztropine Comtan® levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT selegiline tablets trihexyphenidyl	*Azilect®* *amantadine tablets* *carbidopa* *Duopa™* *entacapone* *Gocovri™* *levodopa/carbidopa/entacaone* *Lodosyn®* *Osmolex™ ER* *rasagiline* *Rytary™* *selegiline capsules* *Sinemet®* *Sinemet® CR* *Stalevo®* *Tasmar®* *tolcapone* *Xadago® QL* *Zelapar™*

Bladder Relaxants

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 *Bladder Relaxants* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Bladder Relaxants	oxybutynin QL oxybutynin ER QL Toviaz™ QL VESIcare® QL	*darifenacin ER* QL *Detrol®* QL *Detrol® LA* QL *Ditropan® XL* QL *Enablex®* QL *flavoxate* QL *Gelnique™* CC, QL *Myrbetriq™* QL *Oxytrol®* QL *tolterodine* QL *tolterodine ER* QL *trospium* QL *trospium ER* QL

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	tetrabenazine	*Austedo®* *Ingrezza®* *Xenazine®*

Neuropathic Pain

Class Selection & Guidelines

- DMS to select preferred agent(s) based upon economic evaluation; however, at least 2 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 *Neuropathic Pain* class, should require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Neuropathic Pain	duloxetine DR (generic Cymbalta®) gabapentin capsules, solution, tablets QL Lyrica® capsules CC, QL Lyrica oral solution CC	*Cymbalta®* *DermacinRx PHN Pak™* *duloxetine (generic Irenka™)* *Gralise™* *Horizant®* *lidocaine 5% patch CC, QL* *Lidoderm® QL* *Lyrica® CR QL* *Neurontin® QL* *Savella®* (grandfathering allowed)

Pulmonary Arterial Hypertension

Class Selection & Guidelines

- 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 will 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	Letairis™ sildenafil CC Tracleer® 62.5 and 125 mg tablets Ventavis®	*Adcirca™* *Adempas® CC* *Opsumit®* *Orenitram ER™* *Revatio™* *Tracleer® 32 mg tablets for suspension* *Tyvaso™* *Uptravi® QL*

Platelet Aggregation Inhibitors

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 *Platelet Aggregation Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Platelet Aggregation Inhibitors	Aggrenox® Brilinta™ CC cilostazol clopidogrel dipyridamole prasugrel	*aspirin/dipyridamole* *Effient™* *Plavix®* *ticlopidine* *Zontivity™ CC*

Stimulants and Related Agents

Class Selection & Guidelines

Narcolepsy Agents

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

Stimulants and Related Agents

- 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 *Stimulants and Related Agents* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Narcolepsy Agents	Provigil® CC, QL	*armodafinil QL* *modafinil QL* *Nuvigil® QL* *Xyrem® QL*

Drug Class	Preferred Agents	Non-Preferred Agents
Stimulants and Related Agents	Adderall XR® CC, QL Aptensio XR® (methylphenidate ER capsules) CC, QL atomoxetine CC, QL dexmethylphenidate CC, QL dextroamphetamine CC, QL Focalin XR® CC, QL guanfacine ER CC, QL methylphenidate tablets CC, QL mixed amphetamine salts tablets CC, QL Quillivant XR® (methylphenidate ER suspension) CC, QL Vyvanse® capsules, chewable tablets CC, QL	*Adderall® QL* *Adzenys ER™* *Adzenys XR-ODT™ QL* *clonidine ER QL* *Concerta® QL* *Cotempla XR-ODT™ QL* *Daytrana® QL* *Desoxyn® QL* *Dexedrine® QL* *dexmethylphenidate ER QL* *dextroamphetamine ER QL* *dextroamphetamine solution QL* *Dyanavel® XR QL* *Evekeo® QL* *Focalin® QL* *Intuniv® QL* *Kapvay® QL* *Metadate® ER QL* *methamphetamine QL* *Methylin® solution QL* *methylphenidate CD (generic for Metadate CD®) QL* *methylphenidate chewable tablets QL* *methylphenidate ER tablets QL* *methylphenidate ER OROS (generic Concerta®) QL* *methylphenidate LA (generic Ritalin LA®) QL* *methylphenidate solution QL* *mixed amphetamine salts ER QL* *Mydayis™ QL* *ProCentra® QL* *QuilliChew ER™ QL* *Relexxii QL* *Ritalin® QL* *Ritalin LA® QL* *Strattera® QL* *Zenzedi® QL*

Classes Reviewed by Consent Agenda

No change in PDL status:

- Alzheimer's Agents
- Angiotensin Modulator Combinations
- Angiotensin Modulators:
- Antialcoholic Preparations
- Antianginal & Anti-Ischemic
- Antiarrhythmics, Oral
- Anticoagulants
- Antidepressants, Other
- Antidepressants, SSRIs
- Antidepressants, Tricyclics
- Antimigraine Agents - Triptans
- Antipsychotics
- Anxiolytics
- Beta Blockers
- BPH Treatments
- Calcium Channel Blockers
- Lipotropics, Other
- Lipotropics, Statins
- Sedative Hypnotics
- Skeletal Muscle Relaxants
- Smoking Cessation