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 **March 15, 2018**, and the recommendations delivered by the P&T Committee members in attendance.

New Products to Market

Trelegy Ellipta – Non-prefer in the PDL class: *COPD Agents*
Length of Authorization: 1 year

Trelegy Ellipta is a combination of fluticasone furoate (an inhaled corticosteroid), umeclidinium (an anticholinergic), and vilanterol (a long-acting beta$_2$-adrenergic agonist). It is indicated for the long-term, once-daily, maintenance treatment of chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema. It is not indicated for the relief of acute bronchospasm or the treatment of asthma.

Criteria for Approval:

- Diagnosis of chronic obstructive pulmonary disease (COPD); AND
- Failure of at least a 2-week trial with 2 different dual combination products (e.g., inhaled corticosteroid plus long-acting beta-agonist, long-acting beta-agonist plus long-acting muscarinic antagonist).

Age Limit: ≥ 18 years
Quantity Limit: 1 inhalation per day (1 inhaler per 30 days)

Drug Class	Preferred Agents	Non-Preferred Agents
COPD Agents	albuterol-ipratropium inhalation solution QL	*Anoro® Ellipta® QL*
	Atrovent® HFA QL	*Daliresp™ CC, QL*
	Bevespi Aerosphere™ QL	*Incruse™ Ellipta® QL*
	Combivent® Respimat® QL	*Seebri™ Neohaler® CC, QL*
	ipratropium inhalation solution QL	*Spiriva® Respimat® QL*
	Spiriva Handihaler® QL	*Trelegy Ellipta CC, QL*
	Stiolto™ Respimat® QL	*Tudorza™ Pressair™ QL*
		Utibron™ Neohaler® CC, QL

Verzenio™ – Prefer with Clinical Criteria in the PDL class: *Oral Oncology Agents, Breast Cancer*
Length of Authorization: 1 year

Verzenio™ (abemaciclib) is a cyclin-dependent kinase 4 and 6 inhibitor. It is indicated, in combination with fulvestrant, for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Criteria for Approval:

- Diagnosis of advanced or metastatic breast cancer that is:
  - Hormone receptor (HR)-positive; AND
  - Human epidermal growth factor receptor 2 (HER2)-negative; AND

Renewal Criteria:

- Documentation of lack of disease progression or decrease in tumor size.

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

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology Agents, Breast	anastrozole exemestane Ibrance® QL Kisqali® CC, QL letrozole tamoxifen citrate Tykerb® QL Verzenio™ CC, QL Xeloda®	*Arimidex®* *Aromasin®* *capacetabine* *cyclophosphamide* *Fareston®* *Faslodex®* *Femara®*

Calquence® – Non-prefer in the PDL class: *Oral Oncology Agents, Hematologic Cancer*
Length of Authorization: 6 months

Calquence® (acalabrutinib), an irreversible Bruton's tyrosine kinase inhibitor, is indicated for the treatment of adult patients with mantle cell lymphoma who have received at least 1 prior therapy.

Criteria for Approval:

- Diagnosis of advanced mantle cell lymphoma (MCL); AND
- Using acalabrutinib as a single agent; AND
- Trial and failure of at least 1 prior therapy for mantle cell lymphoma; AND
- Naïve to treatment with a Bruton's tyrosine kinase (BTK) inhibitor (acalabrutinib or ibrutinib). Note: does not apply to renewal authorizations.

Renewal Criteria:

- Patient continues to meet initial review criteria; AND
- Documentation of disease stabilization or decrease in size or spread of tumor(s).

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

Drug Class	Preferred Agents	Non-Preferred Agents
Oral Oncology, Hematologic Cancer	Alkeran® Gleevec® QL hydroxyurea Imbruvica™ CC, QL Jakafi™ CC, QL Leukeran® mercaptopurine Purixan® Rydapt® CC, QL Sprycel® QL Zolinza® QL Zydelig® CC, QL	*Bosulif® QL* *Calquence® CC, QL* *Farydak® QL* *Hydrea®* *Iclusig™ QL* *imatinib QL* *Leustatin®* *melphalan* *Ninlaro™* *Purinethol®* *Tasigna® QL* *Venclexta® QL*

Vyzulta™ – Non-prefer in the PDL class: *Ophthalmic Prostaglandin Agonists*

Length of Authorization: 1 year

Vyzulta™ (latanoprostene bunod) is a prostaglandin analogue approved for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Criteria for Approval:

- Diagnosis of open-angle glaucoma or ocular hypertension; AND
- At least 1-month trial of at least 1 preferred prostaglandin analog (e.g., latanoprost).

Age Limit: ≥ 17 years

Quantity Limit: 1 bottle per 30 days

Drug Class	Preferred Agents	Non-Preferred Agents
Ophthalmic Prostaglandin Agonists	latanoprost QL	*bimatoprost QL* *Lumigan® QL* *Rescula® QL* *Travatan Z® QL* *travoprost QL* *Vyzulta™ CC, QL* *Xalatan® QL* *Zioptan® QL*

Full Class Reviews

Antibiotics: GI

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

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: GI	metronidazole tablets vancomycin Xifaxan® CC, QL	*Alinia®* *Dificid®* *Flagyl®* *metronidazole capsules* *neomycin* *paromomycin* *Tindamax®* *tinidazole* *Vancocin®*

Antibiotics: Vaginal

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

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Vaginal	Cleocin® Ovules Clindesse® Vandazole®	*Cleocin® cream* *clindamycin vaginal 2% cream* *MetroGel Vaginal®* *metronidazole vaginal 0.75% gel* *Nuvessa®*

Antifungals: Oral

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 *Antifungals: Oral* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Antifungals: Oral	clotrimazole fluconazole griseofulvin suspension nystatin suspension, tablets terbinafine	*Ancobon®* *Cresemba®* *Diflucan®* *flucytosine* *griseofulvin microsize* *griseofulvin ultramicrosize* *Gris-PEG®* *itraconazole* CC *ketoconazole* *Lamisil®* *Noxafil®* *nystatin powder* *Onmel™* *Oravig™* *Sporanox®* *Vfend®* *voriconazole*

COPD Agents

Class Selection & Guidelines

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

Drug Class	Preferred Agents	Non-Preferred Agents
COPD Agents	albuterol-ipratropium inhalation solution QL Atrovent® HFA QL Bevespi Aerosphere™ AE, QL Combivent® Respimat® QL ipratropium inhalation solution QL Spiriva Handihaler® QL Stiolto™ Respimat® QL	*Anoro® Ellipta® QL* *Daliresp™ CC, QL* *Incruse™ Ellipta® QL* *Seebri™ Neohaler® CC, QL* *Spiriva® Respimat® QL* *Trelegy Ellipta CC, QL* *Tudorza™ Pressair™ QL* *Utibron™ Neohaler® CC, QL*

Antibiotics: Quinolones

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

New agent in the class: **Baxdela™**

Non-prefer in this class.

Length of Authorization: Date of Service (up to 14 days)

Baxdela™ (delafloxacin) a fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible bacteria.

Criteria for Approval:

- Failure of at least a 3-day trial to 1 preferred medication; OR
- Infection is caused by an organism resistant to medications not requiring prior approval (must submit culture and sensitivity information); OR
- Patient is completing a course of therapy which was initiated in the hospital.

Age Limit: ≥ 18 years

Quantity Limit: 2 tablets per day

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Quinolones	ciprofloxacin tablets levofloxacin tablets	*Avelox®* *Baxdela™ AE, QL* *ciprofloxacin ER* *ciprofloxacin suspension* *Cipro®* *Cipro XR®* *Levaquin®* *levofloxacin solution* *moxifloxacin* *ofloxacin*

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

New agent in the class: **Symproic®**

Non-prefer in this class.

Length of Authorization: 1 year

Symproic® (naldemedine tosylate), an opioid antagonist, is indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.

Criteria for Approval:

- Diagnosis of opioid-induced constipation related to chronic non-cancer pain; AND
- Patient has been using opioids for at least 150 days within past 180 days; AND
- Trial and failure of at least 1 preferred GI Motility agent; AND
- Patient does NOT have any the following conditions:
  - Known or suspected gastrointestinal obstruction
  - Pregnancy
  - Severe hepatic impairment (Child-Pugh Class C)

Age Limit: ≥18 years

Quantity Limit: 1 tablet per day

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

Hypoglycemics, Incretin Mimetics/Enhancers

Class Selection & Guidelines

Diabetes: Amylin Analogue

- 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 *Diabetes: Amylin Analogue* class, require PA until reviewed by the P&T Committee

Diabetes: DPP-4 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 will require PA.
- For any new chemical entity in the *Diabetes: DPP-4 Inhibitors* class, require PA until reviewed by the P&T Committee.

Diabetes: GLP-1 Receptor 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 will require PA.
- For any new chemical entity in the *Diabetes: GLP-1 Receptor Agonists* class, require PA until reviewed by the P&T Committee.

New agent in the class: Ozempic®

Non-prefer in this class.

Length of Authorization: 1 year

Ozempic® (semaglutide) is a glucagon-like peptide 1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Criteria for Approval:

- Diagnosis of type 2 diabetes mellitus; AND
- Trial and failure of, or contraindication to, metformin; AND
- Trial (≥ 3 months) and failure of a preferred GLP-1 receptor agonist.

Age Limit: ≥18 years

Quantity Limits: 1 package per 28 days

- 0.25 or 0.5 mg pens: 1 pen per 28 days
- 1 mg pens: 2 pens per 28 days

Drug Class	Preferred Agents	Non-Preferred Agents
Diabetes: Amylin Analogue	N/A	*Symlin® ST*
Diabetes: DPP-4 Inhibitors	Glyxambi® CC, QL Janumet™ CC, QL Janumet XR™ CC, QL Januvia™ CC, QL Jentadueto® CC, QL Tradjenta™ CC, QL	*alogliptin* *alogliptin/metformin* *alogliptin/pioglitazone* *Jentadueto® XR QL* *Kazano® QL* *Kombiglyze™ XR QL* *Nesina® QL* *Onglyza™ QL* *Oseni® QL* *Qtern®*
Diabetes: GLP-1 Receptor Agonists	Byetta™ CC Bydureon® pen, vial CC Victoza® CC	*Adlyxin™ CC, QL* *Bydureon® BCise™* *Ozempic® CC, QL* *Soliqua™ CC, QL* *Tanzeum™* *Trulicity™* *Xultophy® CC, QL*

Diabetes: SGLT2 Inhibitors

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 will require PA.
- For any new chemical entity in the *Diabetes: SGLT2 Inhibitors* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Diabetes: SGLT2 Inhibitors	Invokana® ST Jardiance® CC Synjardy® CC	*Farxiga™* *Invokamet™ – grandfathering allowed* *Invokamet® XR QL* *Synjardy® XR* *Xigduo™ XR*

Classes Reviewed by Consent Agenda

No change in PDL status:

- Absorbable Sulfonamides
- Antibiotics, Inhaled
- Antipsoriatics, Topical
- Cephalosporins and Related Antibiotics
- Hypoglycemics, Alpha-Glucosidase Inhibitors
- Hypoglycemics, Insulins & Related
- Hypoglycemics, Meglitinides
- Hypoglycemics, Metformins
- Hypoglycemics, Sulfonylureas
- Hypoglycemics, Thiazolidinediones (TZDs)
- Oxazolidinones
- Penicillins

Brand/Generic Switch:

- Ketolides/Macrolides

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Macrolides	azithromycin clarithromycin E.E.S. 200 suspension erythromycin base capsules DR	*clarithromycin ER* *E.E.S 400 tablets* *EryPed* *Ery-tab* *erythromycin base tablets* *erythromycin ethylsuccinate 200mg susp.* *PCE®* *Zithromax®* *Zmax®*

Formulation Movement:

- Tetracyclines

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Tetracyclines	demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 100 mg capsules doxycycline monohydrate tablets, suspension minocycline capsules	*Doryx® and Doryx® MPC* *doxycycline hyclate DR capsules* *doxycycline hyclate DR tablets* *doxycycline IR-DR* *doxycycline monohydrate 75 mg, 150 mg capsules, pack* *Minocin®* *minocycline tablets* *minocycline ER* *Morgidox®* *Oracea™* *Solodyn®* *Targadox™* *tetracycline* *Vibramycin®* *Ximino™*