

## 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<sub>2</sub>-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 <sup>QL</sup>	Anoro <sup>®</sup> Ellipta <sup>®</sup> QL
	Atrovent <sup>®</sup> HFA <sup>QL</sup>	Daliresp <sup>™</sup> CC, QL
	Bevespi Aerosphere <sup>™</sup> QL	Incruse <sup>™</sup> Ellipta <sup>®</sup> QL
	Combivent <sup>®</sup> Respimat <sup>®</sup> QL	Seebri <sup>™</sup> Neohaler <sup>®</sup> CC, QL
	ipratropium inhalation solution <sup>QL</sup>	Spiriva <sup>®</sup> Respimat <sup>®</sup> QL
	Spiriva Handihaler <sup>®</sup> QL	<b>Trelegy Ellipta<sup>CC, QL</sup></b>
	Stiolto <sup>™</sup> Respimat <sup>®</sup> QL	Tudorza <sup>™</sup> Pressair <sup>™</sup> QL
		Utibron <sup>™</sup> Neohaler <sup>®</sup> 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
<b>Oral Oncology Agents, Breast</b>	anastrozole	<i>Arimidex®</i>
	exemestane	<i>Aromasin®</i>
	lbrance® QL	<i>capacetabine</i>
	Kisqali® CC, QL	<i>cyclophosphamide</i>
	letrozole	<i>Fareston®</i>
	tamoxifen citrate	<i>Faslodex®</i>
	Tykerb® QL	<i>Femara®</i>
	Verzenio™ CC, QL	
	Xeloda®	

**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
<b>Antibiotics: GI</b>	metronidazole tablets vancomycin Xifaxan <sup>®</sup> CC, QL	<i>Alinia</i> <sup>®</sup> <i>Dificid</i> <sup>®</sup> <i>Flagyl</i> <sup>®</sup> <i>metronidazole capsules</i> <i>neomycin</i> <i>paromomycin</i> <i>Tindamax</i> <sup>®</sup> <i>tinidazole</i> <i>Vancocin</i> <sup>®</sup>

### 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
<b>Antibiotics: Vaginal</b>	Cleocin <sup>®</sup> Ovules <i>Clindesse</i> <sup>®</sup> <i>Vandazole</i> <sup>®</sup>	<i>Cleocin</i> <sup>®</sup> cream <i>clindamycin vaginal 2% cream</i> <i>MetroGel Vaginal</i> <sup>®</sup> <i>metronidazole vaginal 0.75% gel</i> <i>Nuessa</i> <sup>®</sup>

## 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
<b>Antifungals: Oral</b>	clotrimazole fluconazole griseofulvin suspension nystatin suspension, tablets terbinafine	Ancobon® Cresemba® Diflucan® flucytosine griseofulvin microsize griseofulvin ultramicrosize Gris-PEG® itraconazole <sup>CC</sup> 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
<b>COPD Agents</b>	albuterol-ipratropium inhalation solution <sup>QL</sup> Atrovent <sup>®</sup> HFA <sup>QL</sup> Bevespi Aerosphere <sup>™</sup> AE, QL Combivent <sup>®</sup> Respimat <sup>®</sup> QL ipratropium inhalation solution <sup>QL</sup> Spiriva Handihaler <sup>®</sup> QL Stiolto <sup>™</sup> Respimat <sup>®</sup> QL	Anoro <sup>®</sup> Ellipta <sup>®</sup> QL Daliresp <sup>™</sup> CC, QL Incruse <sup>™</sup> Ellipta <sup>®</sup> QL Seebri <sup>™</sup> Neohaler <sup>®</sup> CC, QL Spiriva <sup>®</sup> Respimat <sup>®</sup> QL Trelegy Ellipta <sup>CC, QL</sup> Tudorza <sup>™</sup> Pressair <sup>™</sup> QL Utibron <sup>™</sup> Neohaler <sup>®</sup> 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<sup>™</sup>

Non-prefer in this class.

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

Baxdela<sup>™</sup> (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
<b>Antibiotics:</b> <b>Quinolones</b>	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 <sup>®</sup> CC Linzess <sup>®</sup> CC Movantik <sup>®</sup> CC	alosetron <sup>CC</sup> Lotronex <sup>®</sup> CC Relistor <sup>®</sup> Symproic <sup>®</sup> CC, QL Trulance <sup>™</sup> CC, QL Viberzi <sup>®</sup> 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<sup>®</sup>

Non-prefer in this class.

#### **Length of Authorization:** 1 year

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

## 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
<b>Diabetes: SGLT2 Inhibitors</b>	Invokana <sup>® ST</sup> <b>Jardiance</b> <sup>® CC</sup> <b>Synjardy</b> <sup>® CC</sup>	<i>Farxiga</i> <sup>™</sup> <b>Invokamet</b> <sup>™</sup> – grandfathering allowed <i>Invokamet</i> <sup>® XR QL</sup> <i>Synjardy</i> <sup>® XR</sup> <i>Xigduo</i> <sup>™ XR</sup>

## 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
<b>Antibiotics: Macrolides</b>	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
<b>Antibiotics: Tetracyclines</b>	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™