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Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 01/01/2021

October 14, 2020
6:30 – 8:00 PM

A Division of the Department of State Treasurer

Role Call

P&T COMMITTEE MEMBERS

- David Konanc, MD
- Matthew K. Flynn, MD
- Jennifer Burch, PharmD
- Peter Robie, MD
- Tony Gurley, RPh, JD
- John B. Anderson, MD, MPH
- John Engemann, MD
- Joseph Shanahan, MD
- Sundhar Ramalingam, MD

PLAN STAFF & VENDORS

State Health Plan

- Natasha Davis
- Caroline Smart
- Dee Jones

Segal Consulting

- Kautook Vyas, PharmD

CVS Caremark

- Renee Jarnigan, RPh
- Stephanie Morrison, PharmD

Ethics Awareness & Conflict of Interest Reminder

In accordance with the NC State Health Plan for Teachers and State Employees' ethics policy, it is the duty of every member of the Pharmacy & Therapeutics Committee, whether serving in a vote casting or advisory capacity, to avoid both conflicts of interest and appearances of conflict.

Does any Committee member have any known conflict of interest or the appearance of any conflict with respect to any manufacturers of any medication to be discussed at today's meeting?

Or, if during the course of the evaluation process if you identify a conflict of interest or the appearance of a conflict.

If so, please identify the conflict or appearance of conflict and refrain from any undue participation in the particular matter involved.

Minutes from Previous Committee Meeting

Instead of reading the minutes, copies were distributed prior to the meeting for your review.

- Are there any additions or corrections to the minutes?
- If not, the minutes will stand approved as is.

Formulary Updates – Effective 01/01/2021

CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes (Uptier/Downtier)
- Formulary Additions (New molecule entries, line extensions)
- New Utilization Management Criteria

Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

Formulary Exclusion Exception Process:

- This process is available to support Plan members who, per their provider, have a medical necessity to remain on an excluded drug.
- There may be circumstances in which the formulary alternatives may not be appropriate for some members. In this case, a member may be approved for the excluded drug with an exception process.
- An exception is defined as a situation where the member has tried and failed (that is, had an inadequate treatment response or intolerance) to the required number of formulary alternatives; or the member has a documented clinical reason such as an adverse drug reaction or drug contraindication that prevents them from trying the formulary alternatives.
- If a member's exception is approved that drug will be placed into Tier 3 or Tier 6 and the member will be subject to the applicable cost share.

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Gastrointestinal/ Laxatives	SUPREP	Availability of additional options for colon cleansing prior to a colonoscopy. Preferred options include peg 3350/electrolytes and Clenpiq (sodium picosulfate-magnesium oxide-citric acid).	4714
Endocrine and Metabolic/ Menopausal Symptom Agents/ Oral	PREMARIN	Availability of a generic oral estrogen option. The preferred option is estradiol.	2892
Topical/ Otic/ Anti-infective/ Anti-inflammatory Combinations	CIPRODEX	Availability of generic otic anti-infective and/or anti-inflammatory options. Preferred options include ciprofloxacin-dexamethasone and ofloxacin otic.	2206

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	VIIBRYD	Availability of additional SSRI options. Preferred options include citalopram, escitalopram, fluoxetine, paroxetine HCl, paroxetine HCl ext-rel, sertraline, and Trintellix (vortioxetine).	1292
Gastrointestinal/ Irritable Bowel Syndrome	AMITIZA	Availability of additional options for the treatment of chronic idiopathic constipation, opioid-induced constipation, IBS with constipation. Preferred options include Linzess (linaclotide), Movantik (naloxegol), and Symproic (naldemedine).	689
Endocrine and Metabolic/ Menopausal Symptom Agents/ Vaginal	INTRAROSA	Availability of additional vaginal estrogen options for the treatment of urogenital symptoms associated with menopause. Preferred options include estradiol and Imvexxy (estradiol).	215

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Ophthalmic/ Anti-Inflammatories/ Nonsteroidal	PROLENSA	Availability of additional ophthalmic anti-inflammatory options. Preferred options include bromfenac, diclofenac, ketorolac, Acuvail (ketorolac tromethamine), Ilevro (nepafenac), and Nevanac (nepafenac).	179
Endocrine and Metabolic/ Menopausal Symptom Agents/ Vaginal	ESTRING	Availability of additional vaginal estrogen options for the treatment of urogenital symptoms associated with menopause. Preferred options include estradiol and Imvexxy (estradiol).	175
Endocrine and Metabolic/ Human Growth Hormones	HUMATROPE	Availability of an additional option for the treatment of growth hormone deficiency. The preferred option is Norditropin (somatropin).	141

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Multiple Sclerosis Agents	TECFIDERA	Availability of additional options for the treatment of relapsing forms of multiple sclerosis. Preferred options include dimethyl fumarate delayed-rel, glatiramer, Aubagio (teriflunomide), Betaseron (interferon beta-1b), Copaxone (glatiramer), Gilenya (fingolimod), Kesimpta (ofatumumab), Mayzent (siponimod), Ocrevus (ocrelizumab), Rebif (interferon beta-1a), Tysabri (natalizumab), Vumerity (diroximel fumarate delayed-rel), and Zeposia (ozanimod).	138

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Acne/ Topical	TAZORAC	<p>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), and Onexton (clindamycin-benzoyl peroxide).</p> <p>Availability of generic options for the topical treatment of plaque psoriasis. Preferred options include calcipotriene ointment and calcipotriene solution.</p>	126

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Respiratory/ Anticholinergics	INCRUSE ELLIPTA	Availability of additional long-acting anticholinergic options for the maintenance treatment of chronic obstructive pulmonary disease. Preferred options include Spiriva (tiotropium) and Yupelri (revefenacin inhalation solution).	117
Endocrine and Metabolic/ Contraceptives/ Vaginal	NUVARING	Availability of additional vaginal contraceptive options. Preferred options on the include ethinyl estradiol-etonogestrel and Annovera (segesterone acetate-ethinyl estradiol).	115
Gastrointestinal/ Irritable Bowel Syndrome	TRULANCE	Availability of an additional option for the treatment of chronic idiopathic constipation and IBS with constipation. Preferred option is Linzess (linaclotide).	93

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Ophthalmic/ Antiallergics	BEPREVE	Availability of additional options for allergic conjunctivitis. Preferred options include azelastine, cromolyn sodium, olopatadine, Lastacaft (alcaftadine), and Pazeo (olopatadine).	91
Topical/ Dermatology/ Acne/ Topical	FABIOR	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), and Onexton (clindamycin-benzoyl peroxide).	79

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Respiratory/ Anticholinergic/ Beta Agonist/ Steroid Inhalant Combinations/ Long Acting	BEVESPI	Availability of additional dual therapy options for the maintenance treatment of chronic obstructive pulmonary disease. Preferred options include Anoro Ellipta (umeclidinium-vilanterol) and Stiolto Respimat (tiotropium-olodaterol).	57
Endocrine and Metabolic/ Menopausal Symptom Agents/ Oral	OSPHENA	Availability of a generic oral estrogen option. The preferred option is estradiol.	56
Gastrointestinal/ Laxatives	GOLYTELY	Availability of additional options for colon cleansing prior to a colonoscopy. Preferred options include peg 3350/electrolytes and Clenpiq (sodium picosulfate-magnesium oxide-citric acid).	42

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Attention Deficit Hyperactivity Disorder	APTENSIO XR	Preferred options include amphetamine-dextroamphetamine mixed salts ext-rel (excluding certain NDCs), methylphenidate ext-rel (excluding certain NDCs), Mydayis (amphetamine-dextroamphetamine mixed salts ext-rel), and Vyvanse (lisdexamfetamine).	46
Analgesics/ Viscosupplements	GEL-ONE	Availability of additional viscosupplement options for osteoarthritis. Preferred options include Durolane, Euflexxa, Gelsyn-3, and Supartz FX.	41
Topical/ Dermatology/ Antipsoriatics	CALCIPOTRIENE/BETAMETHAS ONE	Availability of additional topical options for the treatment of plaque psoriasis. Preferred options include calcipotriene, calcipotriene/desoximetasone, fluocinonide, or Bryhali.	39

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Attention Deficit Hyperactivity Disorder	DAYTRANA	Preferred options include amphetamine-dextroamphetamine ,methylphenidate ext-rel, Mydayis (amphetamine-dextroamphetamine mixed salts ext-rel), and Vyvanse (lisdexamfetamine).	38
Endocrine and Metabolic/ Menopausal Symptom Agents/ Vaginal	FEMRING	Availability of additional vaginal estrogen options for the treatment of urogenital symptoms associated with menopause. Preferred options include estradiol and Imvexxy (estradiol).	31

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Hematologic/ Hematopoietic Growth Factors	UDENYCA	Availability of an additional long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy. The preferred option is Ziextenzo (pegfilgrastim-bmez).	25
Central Nervous System/ Antipsychotics/ Atypicals	INVEGA SUSTENNA	Availability of additional long-acting injectable antipsychotic options. Preferred options include Abilify Maintena (aripiprazole ext-rel injection) and Perseris (risperidone ext-rel injection).	25
Topical/ Otic/ Anti-infective/ Anti-inflammatory Combinations	CIPRO HC	Availability of generic otic anti-infective and/or anti-inflammatory options. Preferred options include ciprofloxacin-dexamethasone and ofloxacin otic.	21

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Ophthalmic/ Antivirals	ZIRGAN	Availability of an additional generic antiviral option. The preferred option is trifluridine.	13
Hematologic/ Hematopoietic Growth Factors	NEULASTA	Availability of an additional long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy. The preferred option is Ziextenzo (pegfilgrastim-bmez).	9
Topical/ Dermatology/ Rosacea	MIRVASO	Availability of additional topical options for the treatment of rosacea. Preferred options include azelaic acid gel, metronidazole gel, Finacea foam (azelaic acid), and Soolantra	7

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Acne/ Topical	AZELEX	Preferred options include adapalene, benzoyl peroxide, clindamycin, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo, and Onexton	6
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	PAXIL; PAXIL CR	Preferred options include citalopram, escitalopram, fluoxetine (except fluoxetine tablet 60 mg and generics for Sarafem), paroxetine HCl, paroxetine HCl ext-rel, sertraline, and Trintellix.	5
Central Nervous System/ Antiparkinsonian Agents	APOKYN	Availability of an additional option for the treatment of “off” episodes (return of Parkinson’s symptoms) in those with advanced Parkinson’s disease. The preferred option is Inbrija (levodopa inhalation powder).	5

Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Attention Deficit Hyperactivity Disorder	ADZENYS ER	Preferred options include amphetamine-dextroamphetamine mixed salts ext-rel (excluding certain NDCs), methylphenidate ext-rel (excluding certain NDCs), Mydayis (amphetamine-dextroamphetamine mixed salts ext-rel), and Vyvanse (lisdexamfetamine).	5
Topical/ Ophthalmic/ Artificial Tears	LACRISERT	Availability of additional options for the treatment of dry eye. Preferred options include Restasis (cyclosporine, emulsion) and Xiidra (lifitegrast).	5
Cardiovascular/ Nitrates/ Oral	ISOSORB DIN TAB 40MG	Availability of additional generic oral nitrate options. Preferred options are isosorbide dinitrate (except 40 mg) and isosorbide mononitrate.	5

Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Endocrine and Metabolic/ Menopausal Symptom Agents/ Oral	MENEST	Availability of a generic oral estrogen option. The preferred option is estradiol.	4
Endocrine and Metabolic/ Acromegaly	SOMAVERT	Availability of an additional option for the treatment of acromegaly. The preferred option is Somatuline Depot (lanreotide acetate).	2
Analgesics/ Viscosupplements	VISCO-3	Availability of additional viscosupplement options for osteoarthritis. Preferred options include Durolane (sodium hyaluronate), Euflexxa (sodium hyaluronate), Gelsyn-3 (sodium hyaluronate), and Supartz FX (sodium hyaluronate).	1

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Cardiovascular/ Pulmonary Arterial Hypertension/ Endothelin Receptor Antagonists	TRACLEER	Availability of additional options for the treatment of pulmonary arterial hypertension. Preferred options include ambrisentan, bosentan, and Opsumit (macitentan).	1
Analgesics/ Opioid Analgesics	OXYMORPHONE TAB ER	Preferred options include fentanyl transdermal, hydrocodone ext-rel, hydromorphone ext-rel, methadone, morphine ext-rel, and Nucynta ER (tapentadol ext-rel), and Xtampza ER (oxycodone ext-re).	0
Antineoplastic Agents/ Multiple Myeloma/ Proteasome Inhibitors	BORTEZOMIB	Availability of additional options for the treatment of multiple myeloma and mantle cell lymphoma. Preferred options on include Ninlaro (ixazomib) and Velcade (bortezomib).	0

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Antineoplastic Agents/ Multiple Myeloma/ Proteasome Inhibitors	KYPROLIS	Availability of additional options for the treatment of relapsed or refractory multiple myeloma. Preferred options include Ninlaro (ixazomib) and Velcade (bortezomib).	0
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	PEXEVA	Availability of additional selective serotonin reuptake inhibitor options. Preferred options include citalopram, escitalopram, fluoxetine (except fluoxetine tablet 60 mg and generics for Sarafem), paroxetine HCl, paroxetine HCl ext-rel, sertraline, and Trintellix.	0
Central Nervous System/ Musculoskeletal Therapy Agents	METAXALONE TAB 400MG	Availability of an additional generic option for the treatment of pain associated with acute musculoskeletal disorders. The preferred option is cyclobenzaprine (except 7.5 mg tablet).	0

Formulary Updates – Product Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Anti-Infectives/ Miscellaneous	DARAPRIM	Availability of a generic option for the treatment of toxoplasmosis. The preferred option is pyrimethamine.	0
Respiratory/ Alpha-1 Antitrypsin Deficiency Agents	ARALAST	Availability of an additional option for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency. The preferred option is Prolastin-C (alpha-1 proteinase inhibitor).	0
Respiratory/ Alpha-1 Antitrypsin Deficiency Agents	GLASSIA	Availability of an additional option for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency. The preferred option is Prolastin-C (alpha-1 proteinase inhibitor).	0

Formulary Updates – Product Exclusions

Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Endocrine and Metabolic/ Acromegaly	SIGNIFOR LAR	Availability of an additional option for the treatment of acromegaly. The preferred option is Somatuline Depot (lanreotide acetate).	0
Topical/ Dermatology/ Acne/ Topical	DIFFERIN LOTION	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), and Onexton (clindamycin-benzoyl peroxide).	0

Formulary Updates – Product Exclusions

QUESTIONS?

Formulary Updates – Uptiers

Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
- All the following products will be moving from a lower tier to a higher tier.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)	Tier
Gastrointestinal/ Antiemetics	VARUBI	Availability of a generic option for the prevention of chemotherapy-induced nausea and vomiting. The preferred option is aprepitant.	11	3
Central Nervous System/ Antipsychotics/ Atypicals	RISPERDAL INJ	Availability of additional long-acting injectable antipsychotic options. Preferred options include Abilify Maintena (aripiprazole ext-rel injection) and Perseris (risperidone ext-rel injection).	5	3
Central Nervous System/ Antipsychotics/ Atypicals	ARISTADA	Availability of additional long-acting injectable antipsychotic options. Preferred options include Abilify Maintena (aripiprazole ext-rel injection) and Perseris (risperidone ext-rel injection).	2	3

Formulary Updates – Uptiers

QUESTIONS?

Formulary Updates – Downtiers

Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	Tier
Antineoplastic Agents/ Kinase Inhibitors	ALECENSA	To provide an option for the treatment of ALK-positive non-small cell lung cancer.	5
Antineoplastic Agents/ Kinase Inhibitors	ALUNBRIG	To provide an option for the treatment of ALK-positive non-small cell lung cancer.	5
Antineoplastic Agents/ Miscellaneous	ERIVEDGE	To provide an option for the treatment of metastatic basal cell carcinoma.	5
Antineoplastic Agents/ Miscellaneous	PERJETA	To provide an additional option for the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer.	5

Formulary Updates – Downtiers

Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	Tier
Antineoplastic Agents/ Multiple Myeloma/ Proteasome Inhibitors	NINLARO	To provide an additional option for the treatment of multiple myeloma.	5
Antineoplastic Agents/ Multiple Myeloma/ Proteasome Inhibitors	VELCADE SDV	To provide an additional option for the treatment of multiple myeloma and mantle cell lymphoma.	5
Central Nervous System/ Anticonvulsants	XCOPRI	To provide an additional option for the treatment of partial-onset seizures.	2
Central Nervous System/ Anticonvulsants	NAYZILAM	To provide an additional option for the treatment of acute, intermittent seizures.	2

Formulary Updates – Downtiers

Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	Tier
Central Nervous System/ Anticonvulsants	VALTOCO	To provide an additional option for the treatment of acute, intermittent seizures.	2
Central Nervous System/ Multiple Sclerosis Agents	OCREVUS	To provide an option for the treatment of primary progressive multiple sclerosis and an additional option for the treatment of relapsing forms of multiple sclerosis.	5
Endocrine and Metabolic/ Contraceptives/ Vaginal	ANNOVERA	To provide an additional vaginal contraceptive option.	2

Formulary Updates – Downtiers

Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	Tier
Endocrine and Metabolic/ Menopausal Symptom Agents/ Vaginal	IMVEXXY	To provide an additional vaginal option for the treatment of dyspareunia.	2
Gastrointestinal/ Laxatives	CLENPIQ	To provide an additional option for colon cleansing prior to a colonoscopy.	2
Topical/ Ophthalmic/ Prostaglandins	ZIOPTAN	To provide an additional option for reducing elevated intraocular pressure.	2

Formulary Updates – Downtiers

QUESTIONS?

Formulary Updates – Formulary Additions

Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)	Tier
Analgesics/ Viscosupplements	EUFLEXXA	To provide an additional viscosupplement option for osteoarthritis.	NA	2
Analgesics/ Viscosupplements	DUROLANE	To provide an additional viscosupplement option for osteoarthritis.	NA	2
Antineoplastic Agents/ Miscellaneous	PHESGO SOL	To provide an additional option for the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer.	NA	5
Central Nervous System/ Anticonvulsants	LAMICTAL	To provide an additional option for the treatment of seizures.	NA	3

Formulary Updates – Formulary Additions

Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)	Tier
Central Nervous System/ Antipsychotics/ Atypicals	PERSERIS INJ	To provide a long-acting injectable antipsychotic option.	NA	2
Endocrine and Metabolic/ Antidiabetics/ Insulins	TOUJEO	To provide an additional long-acting insulin option for the management of diabetes mellitus.	NA	2
Endocrine and Metabolic/ Human Growth Hormones	NORDITROPIN	To provide an option for the treatment of growth hormone deficiency.	NA	5
Hematologic/ Hematopoietic Growth Factors	ZIEXTENZO	To provide a long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	NA	5

Formulary Updates – Formulary Additions

Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)	Tier
Hematologic/ Thrombocytopenia Agents	DOPTELET	To provide an additional option for the treatment of thrombocytopenia.	NA	5
Topical/ Ophthalmic/ Anti- Inflammatories/ Steroidal	FLAREX	To provide an additional option for ocular inflammation.	NA	3

Formulary Updates – Formulary Additions

QUESTIONS?

Formulary Updates – New Molecular Entities

Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
LAMPIT (nifurtimox)	Indicated for use in pediatric patients (birth to <18; weighing at least 2.5kg) for treatment of Chagas disease.	No utilization management	3
ORIAHNN (elagolix, estradiol and norethindrone; elagolix)	Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.	When prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a premenopausal patient AND The patient has not already received greater than or equal to 24 months of therapy of the requested drug	2

Formulary Updates – New Molecular Entities

Formulary Additions

Drug	Indication	Criteria for Approval	Tier
INBRIJA (levodopa inhalation)	Indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.	<p>6 month authorization when the following criteria are met:</p> <p>A. The member experiences at least 2 hours per day of off time</p> <p>B. The member is currently being treated with oral carbidopa/levodopa</p> <p>C. Attempts to manage off episodes by adjusting the dosing or formulation of carbidopa/levodopa were ineffective</p> <p>D. Treatment with carbidopa/levodopa plus one of the following therapies was ineffective at managing off episodes:</p> <ol style="list-style-type: none"> 1. Dopamine agonist (e.g., pramipexole, ropinirole) 2. Monoamine oxidase B (MAO-B) inhibitor (e.g., selegiline, rasagiline) 3. Catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone, tolcapone) 	5

Formulary Updates – New Molecular Entities

Formulary Additions

Drug	Indication	Criteria for Approval	Tier
INBRIJA (levodopa inhalation) - continued	Indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.	Exclusions: Asthma; COPD; chronic underlying lung dz; concomitant tx with non-selective MAOIs Quantity Limits: 60 cap carton: 5 cartons/30 DS 92 cap carton: 4 cartons/30 DS	5

Formulary Updates – New Molecular Entities

Formulary Additions

Drug	Indication	Criteria for Approval	Tier
XOSPATA (gilteritinib)	Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.	12 month authorization may be granted with documentation of FLT3 mutation for tx of FLT3 mutation-positive relapsed or refractory AML when med is used as a single-agent. QL: 90/30 days supply	5
BALVERSA (erdafinitinib)	Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has either susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.	12 month auth may be granted for tx of recurrent, locally advanced or metastatic urothelial carcinoma with documentation of susceptible FGFR3 or FGFR2 genetic alteration AND the med requested is following at least one line of prior platinum-containing chemotherapy OR checkpoint inhibitor therapy. QL: 3mg – 84/28 days 4mg – 56/28 days 5mg – 28/28 days	6

Formulary Updates – New Molecular Entities

Formulary Additions

Drug	Indication	Criteria for Approval	Tier
ROZLYTREK (entrectinib)	Indicated for the treatment of adults with NSMLC whose tumors are ROS-1 positive; AND for adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.	12 month authorization granted when the following criteria are met: A. SOLID TUMORS: 1. Lab testing (NGS or FISH) demonstrating tumors have NTRK gene fusion w/o acquired resistance mutation; 2. metastatic dz OR surgical resection with severe morbidity risk; 3. no satisfactory alts OR disease has progressed with standard systemic tx. B. NSCLC: Tx of ROS1-positive NSCLC. QL: 100 mg – 30/30days; 200mg – 90/30days	6

Formulary Updates – New Molecular Entities

Formulary Additions

Drug	Indication	Criteria for Approval	Tier
ZEPOSIA (ozanimod)	Indicated for the treatment of relapsing forms of MS in adults including clinically isolated syndrome (CIS); relapsing-remitting MS (RRMS); and active secondary progressive MS (SPMS).	12 month auth with diagnosis of relapsing MS (including RRMS and SPMS) or for treatment of CIS. QL of 1 starter pack per 37 days or 30 caps/30 days	5
KESIMPTA (ofatumumab)	Indicated for the treatment of relapsing forms of MS in adults including CIS, RRMS and SPMS.	12 month auth with diagnosis of relapsing MS (including RRMS and SPMS) or for treatment of CIS. Concomitant use of Kesimpta with other disease modifying multiple sclerosis agents will not be approved. (Note: Ampyra and Nuedexta are not disease modifying).	5

Formulary Updates – New Molecular Entities

Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
<p>NEXLETOL (bempedoic acid)</p> <p>NEXLIZET (bempedoic acid and ezetimibe)</p>	<p>Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.</p>	<p>ST or PA Criteria Available:</p> <p>ST requires use of 30 DS of a statin with last 120 days, if not claim rejects and requires PA. Criteria for PA approval:</p> <p>prescribed for the treatment of an adult patient with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease</p> <p>AND</p> <p>being prescribed as an adjunct to maximally tolerated statin therapy</p> <p>AND</p> <p>patient requires additional lowering of low-density lipoprotein cholesterol (LDL-C)</p>	<p>2</p>

Formulary Updates – New Molecular Entities

QUESTIONS?

Formulary Updates – Line Extensions

Line Extensions

- These are new formulations or strengths of existing formulary medications being added to the formulary.

Drug	Tier
ARAZLO LOT 0.045%	3
BENLYSTA INJ 200MG/ML	6
BREZTRI AEROSPHERE	2
PACLITAXEL INJ 100/16.7	3
PARAPLATIN INJ 1000MG	3
TRULICITY INJ	3

Formulary Updates – Line Extensions

QUESTIONS?

Summary of Formulary Changes Effective 01/01/21

PRODUCT EXCLUSIONS

- 50 products were excluded impacting 13,751 members

UPTIERS/DOWNTIERS

- 17 products (3 uptiers) had movement impacting approximately 18 members

FORMULARY ADDITIONS

- 10 products were added to the formulary including formulary add backs.

NEW MOLECULAR ENTITIES

- 10 new drug products were added to the formulary.

LINE EXTENSIONS

- 6 products had additional strengths and formulations added to the formulary.



Next meeting: **February 10, 2021**



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