North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

STATE TREASURER OF NORTH CAROLINA
DALE R. FOLWELL, CPA

Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 1/1/19

October 23, 2018
6:30 – 8:00 PM

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

- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones

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.

Recent Plan Formulary Decisions

- All approved negative formulary changes from August's meeting went into effect 10/1/2018 and include the following:
  - Removed the following products from the formulary:
    - LAZANDA, ZOLPIMIST, levorphanol, fluocinonide 0.1% cream hydrocortisone 1% in Absorbase, & benzonatate 150 mg capsules.
  - Moved the following branded products to non-preferred status:
    - BENZACLIN, MIRAPREX, MINASTRIN 24 FE chewables, APTENSIO XR, & QUILLIVANT XR.
  - Adopted the following new utilization management criteria:
    - Nuedexta Initial Prior Authorization
    - Topical NSAIDs Initial Prior Authorization with Quantity Limit
    - Chenodal Initial Prior Authorization
    - Naprelan Initial Prior Authorization
    - Thiola Initial Prior Authorization

Minutes from Previous Committee Meeting

- Instead of having the Secretary read the minutes, copies have been distributed for your review.
- They are located just after the conflict of interest statement in the P&T Booklet that was attached to your meeting invite.
- Are there any additions or corrections to the minutes?
  - If not, the minutes will stand approved as is.

2019 Formulary Strategy

Standard Control Formulary Removals	
Drug Class	**Removed Medications**
Antiemetic	Zuplenz
Anti-Infective	Acticlate, Targadox
Anti-Obesity Oral	Contrave
Antipsoriatics	Sorilux
CNS	Vanatol LQ/Vanatol S
DPP4 and biguanide combinations	Jentadueto/XR, Tradjenta
Growth Hormone	Norditropin
Hemophilia VIII	Eloctate
Hemophilia IX	Alprolix
Migraine NSAID	Cambia
Ophthalmic	Avenova
Pulmonary Enzyme Deficiency	Prolastin C, Zemaira
Severe Asthma	Fasenra
SGLT2 and biguanide combinations	Invokana and Invokamet/XR
Thyroid Agents	Tirosint
Topical Derm Acne	Acanya, Benzaclin, Onexton, Veltin, Ziana

Standard Control Formulary Add Backs	
Drug Class	**Added Back Medications**
Autoimmune	Xelijanz/XR
Growth Hormone	Genotropin
SGLT2 and biguanide combinations	Jardiance, Synjardy/XR

Formulary Updates – Effective 1/1/2019

CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes
- New Drug Additions
- Utilization Management Criteria

Presented by:

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

Formulary Updates – Product Exclusions

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
CONTRAVE (naltrexone/bupropion)	Endocrine and Metabolic/ Antiobesity/ Oral	Availability of additional adjunctive options for weight management. Preferred options include Belviq (lorcaserin), Belviq XR (lorcaserin ext-rel), and Saxenda (liraglutide).	Exclude	2--> Not Covered	1226
JENTADUETO (linagliptin/metformin)	Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/Biguanide Combinations	Availability of additional options for the treatment of type 2 diabetes mellitus. Preferred options include Janumet (sitagliptin-metformin) and Janumet XR (sitagliptin-metformin ext-rel).	Exclude	2--> Not Covered	78
JENTADUETO XR (linagliptin/metformin ext-rel)	Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/Biguanide Combinations	Availability of additional options for the treatment of type 2 diabetes mellitus. Preferred options include Janumet (sitagliptin-metformin) and Janumet XR (sitagliptin-metformin ext-rel).	Exclude	2--> Not Covered	102
TRADJENTA (linagliptin)	Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	Availability of additional options for the treatment of type 2 diabetes mellitusdiabetes. The preferred option is Januvia (sitagliptin).	Exclude	2--> Not Covered	679
ACANYA GEL (benzoyl peroxide 2.5% and clindamycin 1.2%)	Topical/ Dermatology/ Acne/ Topical	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).	Exclude	2--> Not Covered	18
BENZACLIN GEL (benzoyl peroxide 5% and clindamycin 1%)	Topical/ Dermatology/ Acne/ Topical	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).	Exclude	3--> Not Covered	12

Formulary Updates – Product Exclusions

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
ONEXTON GEL (benzoyl peroxide 3.75% and clindamycin 1.2%)	Topical/ Dermatology/ Acne/ Topical	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).	Exclude	3--> Not Covered	60
VELTIN GEL (clindamycin 1.2% and tretinoin 0.025%)	Topical/ Dermatology/ Acne/ Topical	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).	Exclude	3--> Not Covered	54
ZIANA GEL (clindamycin 1.2% and tretinoin 0.025%)	Topical/ Dermatology/ Acne/ Topical	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).	Exclude	3--> Not Covered	15
CAMBIA (diclofenac)	Analgesics/ NSAIDs	Availability of generic nonsteroidal anti-inflammatory agents (NSAIDs) for treating migraines. Preferred options include diclofenac sodium, meloxicam, and naproxen.	Exclude	3--> Not Covered	154
SORILUX (calcipotriene)	Topical/ Dermatology/ Antipsoriatics	Availability of a generic option for the treatment of plaque psoriasis. The preferred option is calcipotriene.	Exclude	3--> Not Covered	15
ACTICLATE (doxycycline)	Anti-Infectives/ Antibacterials/ Tetracyclines	Availability of a generic antibiotic option for the treatment of infections. The preferred option is generic doxycycline hyclate.	Exclude	3--> Not Covered	44
TARGADOX (doxycycline)	Anti-Infectives/ Antibacterials/ Tetracyclines	Availability of a generic antibiotic option for the treatment of infections. The preferred option is generic doxycycline hyclate.	Exclude	3--> Not Covered	55

Formulary Updates – Product Exclusions

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
ZUPLENZ (ondansetron)	Gastrointestinal/ Antiemetics	Availability of additional options for the prevention of nausea and vomiting. Preferred options include granisetron, ondansetron, and Sancuso (granisetron transdermal).	Exclude	3--> Not Covered	7
VANATOL LQ (butalbital, acetaminophen and caffeine)	Analgesics/ Non-Opioid Analgesics	Availability of generic options for the relief of tension headache. Preferred options include diclofenac sodium and naproxen.	Exclude	3--> Not Covered	1
TIROSINT (levothyroxine)	Endocrine and Metabolic/ Thyroid Supplements	Availability of additional options for the treatment of hypothyroidism. Preferred options include levothyroxine and Synthroid (levothyroxine).	Exclude	3--> Not Covered	247
AVENOVA SOL NEUTROX (pure hypochlorous acid, 0.01%)	Topical/ Ophthalmic/ Miscellaneous	Availability of additional options for eyelid cleansing and removal of microorganism and debris. Consult doctor for preferred options.	Exclude	3--> Not Covered	113
CIMZIA KIT (certolizumab pegol)	Immunologic Agents/ Autoimmune Agents	Availability of additional options for the treatment of ankylosing spondylosis (AS), Crohn's Disease (CD), psoriasis (Ps), psoriatic arthritis (PsA), and rheumatoid arthritis (RA). Preferred options include: • Ankylosing spondylosis (AS): Cosentyx (secukinumab), Enbrel (etanercept), and Humira (adalimumab) • Crohn's Disease (CD): Humira (adalimumab) and Stelara Subcutaneous (ustekinumab)1 • Psoriasis (Ps): Humira (adalimumab), Otezla (apremilast), Stelara Subcutaneous (ustekinumab), and Taltz (ixekizumab) • Psoriatic Arthritis (PsA): Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast) • Rheumatoid Arthritis (RA): Enbrel (etanercept), Humira (adalimumab), Kevzara (sarilumab), Orencia ClickJect (abatacept), Orencia Subcutaneous (abatacept), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib) 1. After failure of Humira (adalimumab)	Exclude (ACSF)	Tier 2/ ACSF-> Excluded	81

Formulary Updates – Product Exclusions

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
LUPRON DEPOT KIT 7.5MG; 22.5MG; 30MG & 45MG (leuprolide acetate for depot suspension)	Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Luteinizing Hormone-Releasing Hormone (LHRH) Agonists	Availability of an additional option for the treatment of advanced prostatic cancer. The preferred option is Eligard (leuprolide acetate).	Exclude (ACSF)	Tier 2/ ACSF–> Excluded	0
ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein]	Hematologic/ Hemophilia A Agents	Availability of additional management options for adults and children with hemophilia A. Preferred options include Adynovate (antihemophilic factor [recombinant] pegylated), Jivi (antihemophilic factor [recombinant] pegylated-aucl), Kogenate FS (antihemophilic factor [recombinant]), Kovaltry (antihemophilic factor [recombinant]), Novoeight (antihemophilic factor [recombinant]), and Nuwiq (antihemophilic factor [recombinant]).	Exclude (ACSF)	Blocked--> Not Covered/ ACSF	2
ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein]	Hematologic/ Hemophilia B Agents	Availability of additional options for adults and children with hemophilia B. Consult doctor for preferred options.	Exclude (ACSF)	Tier 3–> Not Covered/ ACSF	0
ZEMAÍRA (Alpha -Proteinase Inhibitor [Human])	Respiratory/ Pulmonary Enzyme Deficiency Agents	Availability of additional options for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency. Preferred options include Aralast NP (alpha1-proteinase inhibitor) and Glassia (alpha1-proteinase inhibitor), Prolastin-C (alpha1-proteinase inhibitor).	Exclude (ACSF)	Tier 3–> Not Covered/ ACSF	0
FASENRA (benralizumab)	Respiratory/ Severe Asthma Agents	Availability of an additional maintenance option for severe asthma with an eosinophilic phenotype. The preferred option is Nucala (mepolizumab).	Exclude (ACSF)	Tier 3–> Not Covered/ ACSF	28

Formulary Updates – Product Exclusions

Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

- **CHLORZOXAZONE 250 MG (generic only)**
  - Skeletal Muscle Relaxant
  - Manufactured by *Solubiomix*
  - Average Wholesale Price (AWP): $25.00 per tablet
    - Plan's Average Net Cost per Prescription: >$2,300
  - Number of current NCSHP utilizers: 102
  - Formulary alternatives include:
    - Chlorzoxazone 500 MG scored tablet
    - Other muscle relaxants
  - No clinical advantage over the other alternatives

Formulary Updates – Product Exclusions

Summary

- 23 drugs are being removed from the formulary
- 3093 members will have to change therapies or obtain an exception
  - 0.5% of the Plan's population
  - The removal of Tradjenta and Contrave account for 61% of the members affected
- Removing one generic hyperinflated product at this time
  - Chlorzoxazone

Formulary Updates – Uptiers

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
FENTORA (fentanyl buccal tablet)	Analgesics/ Opioid Analgesics	Availability of additional options for managing breakthrough pain in adults with cancer. Preferred options include fentanyl transmucosal lozenge, Abstral (fentanyl citrate sublingual), and Subsys (fentanyl sublingual spray).	Uptier	2--> 3	4
WELCHOL PAK 3.75GM (colesevelam)	Cardiovascular/ Antilipemics/ Bile Acid Resins	Availability of generic options for the treatment of high cholesterol. The preferred options include cholestyramine and colesevelam.	Uptier	2--> 3	421
PYRIDIUM TAB 100MG (phenazopyridine)	Genitourinary/ Miscellaneous	Availability of additional options for managing symptoms of pain, burning, urgency, frequency and other discomforts associated with irritation of the urinary tract mucosa. The preferred option is OTC phenazopyridine.	Uptier	2--> 3	1
LUPRON DEPOT KIT 3.75MG & 11.25MG (leuprolide acetate for depot suspension)	Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Luteinizing Hormone-Releasing Hormone (LHRH) Agonists	Availability of additional options for the management of endometriosis and uterine leiomyomata (fibroids). Consult doctor for preferred alternatives.	Uptier	Tier 5--> Tier 6/ ACSF	59
ZOLADEX (goserelin acetate)	Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Luteinizing Hormone-Releasing (LHRH) Agonists	Availability of additional options for the treatment of prostate cancer, endometriosis, endometrial-thinning prior to endometrial ablation, or advanced breast cancer. Preferred options include Eligard (leuprolide acetate) for prostate cancer. Consult doctor for preferred options for endometriosis and advanced breast cancer.	Uptier	Tier 5--> Tier 6/ ACSF	0

Formulary Updates – Downtiers

Drug	Therapeutic Category/ Subcategory	Rationale/Alternatives	Change Type	Proposed NC Status/Tier	Utilizers (6 mo)
ARNUITY ELLIPTA (fluticasone furoate)	Respiratory/ Steroid Inhalants	To provide an additional prophylactic option for the treatment of asthma.	Downtier	3--> 2	173
ABSTRAL (fentanyl sublingual)	Analgesics/ Opioid Analgesics	To provide an additional option for managing breakthrough pain in adults with cancer.	Downtier	3--> 2	0
EUCRISA (crisaborole)	Topical/ Dermatology/ Atopic Dermatitis/ Topical	To provide an additional option for the treatment of atopic dermatitis.	Downtier	3--> 2	471
ZEJULA (niraparib)	Antineoplastic Agents/ Miscellaneous	To provide an option for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.	Downtier	Tier 6--> Tier 5/ ACSF	7
ARALAST NP ($alpha_1$-proteinase inhibitor [human])	Respiratory/ Pulmonary Enzyme Deficiency Agents	To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.	Downtier	Tier 6--> Tier 5/ ACSF	0
GLASSIA (alpha1-proteinase inhibitor [human])	Respiratory/ Pulmonary Enzyme Deficiency Agents	To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.	Downtier	Tier 6--> Tier 5/ ACSF	0
NUCALA (mepolizumab)	Respiratory/ Severe Asthma Agents	To provide an option for the treatment of severe asthma or eosinophilic granulomatosis with polyangiitis (EGPA).	Downtier	Tier 6--> Tier 5/ ACSF	50
PROLASTIN-C (alpha1-proteinase inhibitor [human])	Respiratory/ Pulmonary Enzyme Deficiency Agents	To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.	Downtier	Tier 6--> Tier 5/ ACSF	0

Formulary Updates – New Drug Additions

New-to-Market Block Removals

- CVS Health program that initially blocks new drugs from being added to the formulary and evaluates:
  - Drug's place in therapy
  - Potential market share
  - Cost
  - Appropriate utilization management
- CVS adds new drugs to their formulary throughout the year, however the Plan only adds these medications on a quarterly basis

Add-Backs

- Medications that were previously removed from the formulary but are now being added back
- Only occurs once a year
  - Xeljanz, & Xeljanz XR are being added back this year

New Molecular Entities

- Are also initially placed on CVS's New-to-Market Block
- These medications are reviewed by the members of the Plan's P&T Committee to determine:
  - Satisfactory tier position
  - Appropriate utilization management

Formulary Updates – New Drug Additions

Drug	Therapeutic Category/ Subcategory	Rationale	Change Type	Proposed NC Status/Tier	New Molecular Entity
ADYNOVATE (anithemophilic factor [recombinant], PEGylated)	Hematologic/ Hemophilia A Agents	To provide an additional option for the treatment of hemophilia A. Twice-weekly dosing compared to Advate.	Add	Blocked--> Tier 5/ ACSF	No, pegylated version of Advate which is a preferred formulary option.
AJOVY (fremanezumab-vfrm)	Central Nervous System/ Migraine/ Monoclonal Antibody	To provide an additional option for the prevention of migraines.	Add	Blocked--> 2	Yes.
ALIQOPA (copanlisib)	Antineoplastic Agents/ Kinase Inhibitors	To provide an additional option for the treatment of relapsed follicular lymphoma.	Add	Blocked--> Tier 6/ ACSF	Yes.
ALUNBRIG (brigatinib)	Antineoplastic Agents/ Kinase Inhibitors	To provide an additional option for the treatment of ALK+ metastatic NSCLC.	Add	Blocked--> Tier 6/ ACSF	Yes.
AZEDRA (iobenguane I 131)	Antineoplastic Agents/ Miscellaneous	Provides the first FDA-approved drug for the treatment of cancers known as pheochromocytoma and paraganglioma that are positive for the norepinephrine transporter (as determined by an iobenguane scan), and who require systemic anticancer therapy.	Add	Blocked--> Tier 6/ ACSF	Yes.
BORTEZOMIB (bortezomib)	Antineoplastic Agents/ Miscellaneous	Provides an additional option to Velcade.	Add	Blocked--> Tier 6/ ACSF	No, same active ingredient as Velcade (came to market in May 2003); Bortezomib is a single source brand available from a different manufacturer available 12/2017.
BRAFTOVI (encorafenib)	Antineoplastic Agents/ Kinase Inhibitors	Provides an additional option for the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutation w/Mektovi	Add	Blocked--> Tier 6/ ACSF	Yes.
BROMSITE (bromfenac opthalmic solution)	Topical/ Ophthalmic/ Anti-Inflammatories/ Nonsteroidal	First and only topical opthalmic nonsteroidal anti-inflammatory drug (NSAID) indicated to prevent ocular pain after cataract surgery.	Add	Blocked --> 3	No, Brand product of Bromfenac ophthalmic solution - a NSAID; not a new molecular entity but new GPI that was available 10/31/16.
BUPIVACAINE INJ 312.5/10 (bupivacaine)	Central Nervous System/ Local Anesthetics	Provides additional drug coverage.	Add	Blocked --> 3	No, new Single Sourced Brand of bupivicaine; not a new drug entity
BUTAL/APAP CAP 50-300MG (butalbital/acetaminophen)	Central Nervous System/ Migraine	Provides additional drug coverage.	Add	Blocked --> 3	No, new Generic Product Identifier (GPI) but not a new drug entity.

Formulary Updates – New Drug Additions

Drug	Therapeutic Category/ Subcategory	Rationale	Change Type	Proposed NC Status/Tier	New Molecular Entity
DUROLANE (hyaluronic acid)	Analgesics/ Viscosupplements	To provide an additional option for the treatment of knee pain due to osteoarthritis (OA).	Add	Blocked --> 2	No, another Single Sourced Brand formulation of sodium hyaluronate.
EMBEDA (morphine/naltrexone)	Analgesics/ Opioid Analgesics	To provide an additional option for the treatment of severe pain.	Add	Blocked--> 2	No, another abuse-deterrent opioid formulation
EMGALITY (galcanezumab-gnlm)	Central Nervous System/ Migraine/ Monoclonal Antibody	To provide an additional option for the prevention of migraines.	Add	Blocked--> 2	Yes.
EPINEPHRINE INJ 1MG/10ML (epinephrine)	Cardiovascular/ Vasopressors	Provides additional drug coverage.	Add	Blocked --> 3	No, new Generic Product Identifier (GPI) but not a new drug entity.
ERLEADA (apalutamide)	Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Antiandrogens	To provide a new option for the treatment of non-metastatic, castration-resistant prostate cancer.	Add	Blocked--> Tier 5/ ACSF	Yes.
GLYXAMBI (empagliflozin/linagliptin)	Endocrine and Metabolic/ Antidiabetics/ Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor / Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combinations	To provide an additional option to improve glycemic control in adults with type 2 diabetes mellitus.	Add	Blocked--> 2	No, combination product of Jardiance & Tradjenta
IDELVION (coagulation factor IX [recombinant], albumin fusion protein)	Hematologic/ Hemophilia B Agents	To provide an additional option for the treatment of hemophilia B.	Add	Blocked--> Tier 6/ ACSF	No, another Factor IX product - not a new molecular entity
JIVI (antihemophilic factor [recombinant PEGylated-aucl)	Hematologic/ Hemophilia A Agents	To provide an additional option for the treatment of hemophilia A.	Add	Blocked--> Tier 5/ ACSF	No, antihemophilic Factor VIII - not a new molecular entity
KCL/D5W INJ 20/250ML (potassium chloride in 5% dextrose)	Nutritional/Supplements/ Electrolytes	Provides additional drug coverage.	Add	Blocked --> 3	No, new Single Sourced Brand of KCL/D5W; not a new drug entity
KYPROLIS (carfilzomib)	Antineoplastic Agents/ Proteasome Inhibitor	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new 10mg strength; 30 mg and 60 mg strengths already on formulary at tier 6

Formulary Updates – New Drug Additions

Drug	Therapeutic Category/ Subcategory	Rationale	Change Type	Proposed NC Status/Tier	New Molecular Entity
LENVIMA CAP 12MG & 4MG (lenvatinib)	Antineoplastic Agents. Kinase Inhibitors	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new strength; Lenvima already on formulary at tier 6
MEKTOVI (binimetinib)	Antineoplastic Agents/ Kinase Inhibitors	Provides an additional option for the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutation w/Braftovi	Add	Blocked--> Tier 6/ ACSF	Yes.
NERLYNX (neratinib)	Antineoplastic Agents/ Kinase Inhibitors	To provide an additional option for the treatment of early-stage HER2-positive breast cancer	Add	Blocked--> Tier 6/ ACSF	Yes.
NOVAREL INJ 5000UNIT (chorionic gonadotropin)	Endocrine and Metabolic/ Fertility Regulators/ Ovulation Stimulants, Gonadotropins	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new strength - Novarel 10000 unit already on formulary at tier 6
NUPLAZID 34MG & 10MG (pimavanserin)	Central Nervous System/ Antipsychotics/ Atypicals	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new strength
ORKAMBI 100-125 & 150-188 (lumacaftor/ivacaftor)	Respiratory/ Cystic Fibrosis	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new granules packet dosage form; Orkambi Tabs on formulary at T6
PANCREAZE (pancrelipase)	Gastrointestinal/ Pancreatic Enzymes	Provides additional drug coverage.	Add	Blocked --> 3	No, new formulation of pancreatic enzymes
PHENYLEPHRINE INJ 0.8/10ML (phenylephrine)	Cardiovascular/ Vasopressors	Provides additional drug coverage.	Add	Blocked --> 3	No, new Generic Product Identifier (GPI) but not a new drug entity.
POTELIGEO (mogamulizumab-kpkc)	Immunologic Agents/ Monoclonal Antibodies	To provide a new option for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.	Add	Blocked--> Tier 6/ ACSF	Yes.
REBINYN (coagulation factor IX [recombinant], glycoPEGylated)	Hematologic/ Hemophilia Agents	To provide an option for the treatment of hemophilia B.	Add	Blocked--> Tier 5/ ACSF	No, another Factor IX product - not a new molecular entity
RHOPRESSA (netarsudil ophthalmic solution)	Topical/ Ophthalmic/ Miscellaneous	First ROCK inhibitor. Alternatives are latanoprost, Lumigan, Travatan Z.	Add	Blocked --> 2	Yes.
SERNIVO (betamethasone dipropionate)	Topical/ Dermatology/ Corticosteroids/ High Potency	Alternatives include generics desoximetasone, fluocinonide.	Add	Blocked --> 3	No, new formulation of betamethasone - not a new molecular entity
SIGNIFOR LAR INJ 10MG & 30MG (pasireotide)	Endocrine and Metabolic/ Acromegaly	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, new strength of entity already on formulary at tier 6.

Formulary Updates – New Drug Additions

Drug	Therapeutic Category/ Subcategory	Rationale	Change Type	Proposed NC Status/Tier	New Molecular Entity
SIKLOS (hydroxyurea)	Antineoplastic Agents/ Miscellaneous	The first and only hydroxyurea-based treatment for pediatric patients with sickle cell anemia	Add	Blocked--> Tier 6/ ACSF	No, Single Sourced Brand formulation of Hydroxyurea tablet 100mg - not a new molecular entity
TIBSOVO (ivosidenib)	Antineoplastic Agents/ Kinase Inhibitors	First IDH1 inhibitor for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have that specific genetic mutation.	Add	Blocked--> Tier 6/ ACSF	Yes.
ULTRAVATE LOTION 0.05% (halobetasol propionate)	Topical/ Dermatology/ Corticosteroids/ Very High Potency	Provides additional drug coverage.	Add	Blocked --> 3	No, another formulation of halobetasol (lotion).
VANCOMYCIN INJ 250MG (vancomycin)	Anti-Infectives/ Miscellaneous	Provides additional drug coverage.	Add	Blocked --> 3	No, new Single Sourced Brand of 250 mg inj of vancomycin; not a new drug entity
VYXEOS (daunorubicin/cytarabine)	Antineoplastic Agents/ Antimetabolites	Provides additional drug coverage.	Add	Blocked--> Tier 6/ ACSF	No, combo of existing drugs Daunorubicin/Cytarabine - not a new molecular entity
VYZULTA (latanoprostene bunod)	Topical/ Ophthalmic/ Prostaglandins	Alternatives available in preferred brands Lumigan, Travatan Z.	Add	Blocked --> 3	Yes.
XELJANZ (tofacitinib)	Immunologic Agents/ Autoimmune Agents	To provide an additional option for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC).	Add	Not Covered/ ACSF--> Tier 5/ ACSF	No, approved in 2012, additional Janus-associated kinase inhibitor
XELJANZ XR (tofacitinib ext-rel)	Immunologic Agents/ Autoimmune Agents	To provide an additional option for the treatment of rheumatoid arthritis (RA).	Add	Not Covered/ ACSF--> Tier 5/ ACSF	No, approved in 2012, additional Janus-associated kinase inhibitor
ZEMDRI (plazomicin)	Anti-Infectives/ Antibacterials/ Aminoglycosides	To provide an additional option for the treatment of complicated UTI.	Add	Blocked --> 3	Yes.

Formulary Updates – New Drug Additions

AJOVY (fremanezumab-vfrm)

- Indication:
  - Preventive treatment of migraine in adults
- Mechanism of Action:
  - Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist
  - Human monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor
- Drug Facts:
  - 225 mg sub-q monthly or 675 mg every 3 months
  - Very well tolerated, besides pain at injection site & possible hypersensitivity reactions
- Place in Therapy:
  - Second approved anti-CGRP behind AIMOVIG
  - Groundbreaking treatment for migraine patients
- Proposed Tier Placement:
  - Tier 2 – Preferred Brand

Formulary Updates – New Drug Additions

ALIQOPA (copanlisib)

- Indication:
  - Treatment of relapsed follicular lymphoma in adults who have received at least 2 prior systemic therapies
- Mechanism of Action:
  - Phosphatidylinositol 3-Kinase Inhibitor (PI3K)
  - Copanlisib inhibits phosphatidylinositol 3-kinase (PI3K), primarily the P13K-alpha and P13K-delta isoforms which are expressed in malignant B-cells. Copanlisib induces tumor cell death through apoptosis and inhibition of proliferation of primary malignant B cell lines. In addition, copanlisib inhibits several signaling pathways, including B-cell receptor signaling, CXCR12 mediated chemotaxis of malignant B cells, and NFκB signaling in lymphoma cell lines
- Drug Facts:
  - 60 mg IV on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity
  - Avoid concomitant use of strong CYP3A inhibitors, reduce dose to 45 mg
  - *Warnings*: Infection, Hyperglycemia, Hypertension, Pulmonary toxicity, Bone marrow suppression, Dermatologic toxicity, GI toxicity
- Place in Therapy:
  - Provides an additional choice for treatment with relapsed follicular lymphoma
  - Achieved a 59% overall response rate as the first intravenous PI3K inhibitor
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

ALIQOPA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Follicular lymphoma

Authorization of 12 months may be granted for treatment of relapsed follicular lymphoma (FL) when the member has received at least two prior systemic therapies.

Formulary Updates – New Drug Additions

ALUNBRIG (brigatinib)

- Indication:
  - Treatment of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer (NSCLC) in patients who have progressed on or are intolerant to crizotinib
- Mechanism of Action:
  - Anaplastic Lymphoma Kinase Inhibitor; Tyrosine Kinase Inhibitor
  - Brigatinib is a tyrosine kinase inhibitor (TKI) designed to target and inhibit the ALK mutation in NSCLC
- Drug Facts:
  - 90 mg once daily for 7 days; if tolerated, increase dose to 180 mg once daily
  - Many possible drug-drug interactions
  - *Warnings*: Pulmonary toxicity, Cardiac effects, Ocular toxicity, Creatine phosphokinase elevation, GI toxicity, Hyperglycemia, Anaplastic lymphoma kinase testing
- Place in Therapy:
  - The ALTA trial has established ALUNBRIG as a potential second-line treatment option for ALK+ NSCLC, by demonstrating significant efficacy with a manageable safety profile
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

ALUNBRIG Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for the treatment of recurrent or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC for members who have progressed on or are intolerant to crizotinib.

Brain metastases from NSCLC

Authorization of 12 months may be granted for the treatment of brain metastases from ALK-positive NSCLC.

Formulary Updates – New Drug Additions

AZEDRA (iobenguane I 131)

- Indication:
  - Treatment of adults and adolescents age 12 and older with rare tumors of the adrenal gland (pheochromocytoma or paraganglioma) that cannot be surgically removed (unresectable), have spread beyond the original tumor site and require systemic anticancer therapy
- Mechanism of Action:
  - Radioactivel 131 labeled iobenguane, similar in structure to the neurotransmitter norepinephrine
  - AZEDRA is taken up and accumulates within pheochromocytoma and paraganglioma cells, and radiation resulting from radioactive decay of I 131 causes cell death and tumor necrosis
- Drug Facts:
  - Administer intravenously as a dosimetric dose followed by two therapeutic doses administered 90 days apart
  - *Warnings*: Risk from radiation exposure, Myelosuppression, Secondary myelodysplastic syndrome, leukemia and other malignancies, Hypothyroidism, Elevations in blood pressure, Renal toxicity, Pneumonitis, Embryo-Fetal toxicity, Risk of infertility
- Place in Therapy:
  - This is the first FDA-approved drug for this use
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

BRAFTOVI (encorafenib)

- Indication:
  - Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with binimetinib, as detected by an FDA-approved test
  - Encorafenib is not indicated for treatment of wild-type BRAF melanoma
- Mechanism of Action:
  - BRAF Kinase Inhibitor, which stops tumor cell growth
- Drug Facts:
  - 450 mg once daily (in combination with binimetinib) until disease progression or unacceptable toxicity
  - *Warnings*: Malignancy, Hemorrhage, Ocular toxicity, QT prolongation, Dermatologic toxicity, Many drug-drug interactions
- Place in Therapy:
  - Possibly a new standard of care for BRAF-mutant melanoma patients based on median overall survival in a Phase 3 trial (COLUMBUS)
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

MEKTOVI (binimetinib)

- Indication:
  - Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with encorafenib, as detected by an FDA-approved test
- Mechanism of Action:
  - Mitogen-activated extracellular kinase (MEK) inhibitor
- Drug Facts:
  - 45 mg twice daily, ~12 hours apart (in combination with encorafenib) until disease progression or unacceptable toxicity
  - *Warnings*: Cardiotoxicity, Thromboembolism, Ocular toxicity, Pulmonary toxicity, Hepatotoxicity, Rhabdomyolysis, Hemorrhage
- Place in Therapy:
  - Possibly a new standard of care for BRAF-mutant melanoma patients based on median overall survival in a Phase 3 trial (COLUMBUS)
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

BRAFTOVI Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Melanoma

Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:

A. Braftovi is used in combination with binimetinib

B. Tumor is positive for BRAF V600E or V600K mutation

Formulary Updates – New Drug Additions

MEKTOVI Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Melanoma

Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:

A. Mektovi is used in combination with encorafenib

B. Tumor is positive for BRAF V600E or V600K mutation

Formulary Updates – New Drug Additions

EMGALITY (galcanezumab-gnlm)

- Indication:
  - Preventive treatment of migraine in adults
- Mechanism of Action:
  - Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist
  - Human monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor
- Drug Facts:
  - 240 mg subcutaneously as loading dose, then 120 mg once monthly
  - Very well tolerated, besides pain at injection site & possible hypersensitivity reactions
- Place in Therapy:
  - Third approved anti-CGRP behind AIMOVIG & AJOVY
  - Groundbreaking treatment for migraine patients
- Proposed Tier Placement:
  - Tier 2 – Preferred Brand

Formulary Updates – New Drug Additions

ERLEADA (apalutamide)

- Indication:
  - Treatment of non-metastatic, castration-resistant prostate cancer
- Mechanism of Action:
  - Nonsteroidal androgen receptor inhibitor
  - Apalutamide binds directly to the androgen receptor ligand-binding domain to prevent androgen-receptor translocation, DNA binding, and receptor-mediated transcription. Androgen receptor inhibition results in decreased proliferation of tumor cells and increased apoptosis, leading to a decrease in tumor volume.
- Drug Facts:
  - 240 mg once daily (in combination with a gonadotropin-releasing hormone analog agonist or antagonist) until disease progression or unacceptable toxicity
  - *Warnings*: Falls/fractures, Seizures, Dermatologic toxicity, Thyroid dysfunction, Cardiovascular disease, Many drug-drug interactions, QT prolongation
- Place in Therapy:
  - First FDA-approved therapy to treat patients with non-metastatic castration-resistant prostate cancer
- Proposed Tier Placement:
  - Tier 5 – Preferred Specialty

Formulary Updates – New Drug Additions

ERLEADA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Non-metastatic castration-resistant prostate cancer

Authorization of 24 months may be granted for treatment of non-metastatic castration-resistant prostate cancer when Erleada will be administered with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.

Formulary Updates – New Drug Additions

NERLYNX (neratinib)

- Indication:
  - Extended adjuvant treatment of early stage human epidermal growth receptor type 2 (HER2) overexpressed/amplified breast cancer (following adjuvant trastuzumab-based therapy)
- Mechanism of Action:
  - Anti-HER2, Epidermal Growth Factor Receptor (EGFR) inhibitor, Tyrosine kinase inhibitor
  - Targeted therapy that blocks several enzymes that promote cell growth
- Drug Facts:
  - 240 mg once daily for 1 year
  - *Warnings*: GI toxicity, Hepatotoxicity, Many drug-drug interactions,
- Place in Therapy:
  - First extended adjuvant therapy for early-stage, HER2-positive breast cancer
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

NERLYNX Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Breast cancer

Authorization of up to 12 months total may be granted for the treatment of early stage HER2-positive breast cancer when Nerlynx is initiated within two years after completing adjuvant trastuzumab based therapy.

Formulary Updates – New Drug Additions

POTELIGEO (mogamulizumab-kpkc)

- Indication:
  - Treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy
- Mechanism of Action:
  - Monoclonal anti-CC Chemokine Receptor Antibody
  - Binding to CCR4 targets a cell for antibody-dependent cellular cytotoxicity (ADCC), resulting in target cell depletion
- Drug Facts:
  - 1 mg/kg IV on days 1, 8, 15, and 22 of cycle 1, followed by 1 mg/kg IV on days 1 and 15 of each subsequent cycle; continue until disease progression or unacceptable toxicity
  - *Warnings*: Dermatologic toxicity, Infusion reactions, Infections, Autoimmune toxicity, Hematopoietic stem cell transplant, Bone marrow suppression, Polysorbate 80, Many drug-drug interactions
- Place in Therapy:
  - First-in-class defucosylated, humanized IgG1 kappa monoclonal antibody
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

POTELIGEO Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Mycosis fungoides (MF) or Sézary syndrome (SS)

Authorization of 12 months may be granted for treatment of mycosis fungoides (MF) or Sézary syndrome (SS).

Adult T-cell leukemia/lymphoma

Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.

Formulary Updates – New Drug Additions

RHOPRESSA (netarsudil ophthalmic)

- Indication:
  - Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension
- Mechanism of Action:
  - Rho Kinase Inhibitor
  - Although the exact mechanism of action of netarsudil, a rho kinase inhibitor, is unknown, it may reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route.
- Drug Facts:
  - 1 drop in affected eye(s) once daily in the evening
  - *Warnings*: Bacterial keratitis, Remove contact lens
- Place in Therapy:
  - First Rho Kinase inhibitor on the market
  - Provides an additional treatment for patients with open-angle glaucoma and ocular hypertension to lower eye pressure
- Proposed Tier Placement:
  - Tier 2 – Preferred Brand

Formulary Updates – New Drug Additions

VYZULTA (latanoprostene bunod)

- Indication:
  - Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma and ocular hypertension
- Mechanism of Action:
  - Antiglaucoma ophthalmic prostaglandin
  - Latanoprost acid is thought to lower intraocular pressure by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.
- Drug Facts:
  - Instill 1 drop into affected eye(s) once daily in the evening
  - *Warnings*: Ocular effects, Ocular inflammation, Ocular disease, Bacterial keratitis, Contact lens wearers
- Place in Therapy:
  - A new prostaglandin that provides an additional treatment for patients with open-angle glaucoma and ocular hypertension to lower eye pressure
- Proposed Tier Placement:
  - Tier 3 – Non-Preferred Brand

Formulary Updates – New Drug Additions

TIBSOVO (ivosidenib)

- Indication:
  - Treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test
- Mechanism of Action:
  - Isocitrate dehydrogenase 1 (IDH1) enzyme inhibitor
  - Susceptible IDH1 mutations can lead to increased levels of 2-hydroxyglutarate (2-HG) in leukemia cells. 2-HG inhibits alpha-ketoglutarate-dependent enzymes, resulting in impaired hematopoietic differentiation.
- Drug Facts:
  - 500 mg once daily; continue for a minimum of 6 months and then until disease progression or unacceptable toxicity
  - *Warnings*: Differentiation syndrome, QT prolongation, Guillain-Barré syndrome, GI toxicity, Tumor lysis syndrome, Many drug-drug interactions
- Place in Therapy:
  - First Oral, Targeted Therapy for Adult Patients with Relapsed/Refractory Acute Myeloid Leukemia and an IDH1 Mutation
- Proposed Tier Placement:
  - Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

TIBSOVO Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia

Authorization of 12 months may be granted for treatment of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.

Formulary Updates – New Drug Additions

ZEMDRI (plazomicin)

- Indication:
  - Treatment of complicated UTI, including pyelonephritis caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae* in patients ≥18 years of age. Note: Reserve for use in complicated UTI patients who have limited or no alternative treatment options.
- Mechanism of Action:
  - Aminoglycoside antibiotic
  - Interferes with bacterial protein synthesis by binding to 30S ribosomal subunit resulting in a defective bacterial cell membrane.
- Drug Facts:
  - 15 mg/kg IV once daily for 4 to 7 days
  - *Warnings*: Nephrotoxicity, Ototoxicity, Hearing impairment, Neuromuscular blockade, Neuromuscular disorders, Pregnancy, Many drug-drug interactions
- Place in Therapy:
  - The structure of plazomicin protects it from most aminoglycoside-modifying enzymes, which typically inactivate existing aminoglycosides
  - Provides an additional treatment for patients with cUTI who have limited or no alternative treatment options
- Proposed Tier Placement:
  - Tier 3 – Non-Preferred Brand

Utilization Management Policy Review

New Policies Under Consideration

- Corticosteroid-Pulmicort 1mg Post Limit Policy

- Select Prescription Only Medical Devices
  - 510(k) products

Utilization Management Policy Review

Corticosteroid-Pulmicort 1mg Post Limit Policy:

AFFECTED MEDICATIONS

- PULMICORT RESPULES 1MG ONLY

CRITERIA FOR INITIAL APPROVAL

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has the diagnosis of eosinophilic esophagitis (EoE)

AND

- The request is for continuation of therapy with Budesonide (Pulmicort) Respules at a dose of 1mg twice daily (2mg daily), and the patient has been evaluated for improvement or relapse in symptoms or inflammation

OR

- The patient had all of the following: A) Eosinophil-predominant inflammation on biopsy, B) Trial of a proton pump inhibitor (PPI), C) Secondary causes of esophageal eosinophilia were ruled out

The quantity for approval will be 2 packages/60 respules of Budesonide 1 mg (Pulmicort) Respules per month.

Utilization Management Policy Review

Select Medical Devices Initial Prior Authorization:

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements noted in labeling in order to decrease the potential for inappropriate utilization and to confirm the appropriate coverage of select medical devices. A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- intended to affect the structure or any function of the body, and which does not achieve any of its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[1]

This policy is intended to ensure that select medical devices are utilized in accordance with indications or uses within the manufacturer's guidelines and to foster cost-effective, first-line use of available FDA-approved medications and over-the-counter (OTC) products.

In addition, if the patient has experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for the patient's medical condition, the prior authorization will be approved. If criteria for coverage are met, the requested medical device will be approved for 3 months.

Utilization Management Policy Review

Select Medical Devices Initial Prior Authorization:

AFFECTED MEDICATIONS

CLASS	DRUG NAME
Dermatological Products	Loyon, Nuvail 16%, Kamdoy, Emulsion, Epiceram, Entty, Ceracade, Phlag, Eletone, Xeralux, Tetrix, Hylatopic, Neosalus, Neocera, Pruclair, Prumyx, Nivatopic, Dexeryl, Atopiclair, Mb Hydrogel, PR Cream, Alevicyn, Presera, HPR, Tropazone
Antiseborrheic Products	Loutrex, Promiseb
Artificial Saliva	Bocasal, Aquoral, Caphosol, Numoisyn, Aquoral
Wound Dressing	Biafine, Avo Cream, Prutect, Sonafine, Noxifine, Ca Alginate Mis 12" Rope, Curity Hyper Mis 1/2"x15' (Curity Hypertonic Sodium Chloride Packing Strip), Sil-k Pad (Aka Blaine Scarcare Patch)
Oral Wound Care Products	Salicept, Oramagicrx, Mucotrol, Gelx, Mugard
Hyaluronate Products	Bionect, Gelclair
Scar Treatment Products	Celacyn, Recedo, Beau, Restizan, Scar Manage
Eyelid Cleansers	Acuicyn, Ocusoft

Utilization Management Policy Review

Select Medical Devices Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

The requested medical device will be covered with prior authorization when the following criteria are met:

- The medical device is being used according to the manufacturer's indication
- The patient experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

Summary

If approved, the following formulary changes will go into effect 1/1/2019 and include the following:

- DRUG EXCLUSIONS
  - Acanya, Jentadueto, Jentadueto XR, Tradjenta, Contrave, Benzaclin, Onexton, Veltin, Ziana, Cambia, Sorilux, Acticlate, Targadox, Zuplenz, Vanatol LQ, Tirosint, Avenova, Cimzia, Lupron Depot 7.5/22.5/30/45 mg, Eloctate, Alprolix, Zemaira, & Fasenra
- UPTIERS
  - Fentora, Welchol, Pyridium, Lupron Depot 3.75/11.25 mg, & Zoladex
- DOWNTIERS
  - Arnuity Ellipta, Abstral, Eucrisa, Zejula, Aralast Np, Glassia, Nucala, & Prolastin-C
- NEW DRUG ADDITIONS
  - Adynovate, Ajovy, Aliqopa, Alunbrig, Azedra, Bortexomib, Braftovi, Bromsite, Bupivacaine, Butalbital/APAP 50-300 mg, Durolane, Embeda, Emgality, Epinephrine, Erleada, Glyxambi, Idelvion, Jivi, KCL/D5W 20-250 mL, Kyprolis, Lenvima 4/12 mg, Mektovi, Nerlynx, Novarel, Nuplazid, Orkambi, Pancreaze, Phenylephrine, Poteligeo, Rebinyn, Rhopressa, Sernivo, Signifor LAR 10/30 mg, Siklos, Tibsovo, Ultravate, Vancomycin, Vyxeos, Vyzulta, Xeljanz, Xeljanz XR & Zemdri.
- UTILIZATION MANAGEMENT
  - Select Medical Devices, Corticosteroid-Pulmicort 1mg,

Next meeting:
February 19, 2019

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