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STATE TREASURER OF NORTH CAROLINA
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Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 10/1/18

August 21, 2018
6:30 – 8:00 PM

A Division of the Department of State Treasurer

Role Call

VOTING 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

NON-VOTING MEMBERS

- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones
- 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 May's meeting went into effect 8/1/2018 and include the following:
 - **Removed the following products from the formulary:**
 - SYNADERM - hyper inflated product
 - PRALUENT - Advanced Controlled Specialty Formulary exclusion
 - NEUTRASAL - 510(k) product
 - SALIVAMAX - 510(k) product
 - HPR PLUS - 510(k) product
 - **Moved the following branded products to non-preferred status:**
 - Sivextro, Namenda, Coartem, Alinia, Azilect, Beyaz, Lotronex, Voltaren, Fluoxetine, Furadantin, and Parlodel
 - **Adopted the following new utilization management criteria:**
 - EUCRISA Step Therapy
 - ODACTRA Prior Authorization
 - Brand Name Dermatological Topical Corticosteroids 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 emailed out.
- Are there any additions or corrections to the minutes?
 - If not, the minutes will stand approved as is.

2019 Formulary Strategy

- Removing 23 drugs from the formulary
- Adding back 4 drugs to the formulary
- 98.76% of plan members will be able to stay on their current therapy
- Members that will need to change will receive outreach to make the change and ensure continuity of care
- List of all drug changes for 2019 will be available October, 1st 2018
- These will be reviewed at the next P&T meeting: **October, 23rd 2018**

Formulary Updates – Effective 10/1/2018

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

Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives
- **LAZANDA (fentanyl nasal spray)**
 - Opioid agonist indicated for the management of breakthrough pain in cancer patients
 - Average Net Plan Cost = \$1,200 per dispense
 - Number of current NCSHP utilizers: 0
 - Formulary alternatives include:
 - fentanyl transmucosal lozenge
 - Fentora (fentanyl citrate buccal)
 - Subsys (fentanyl sublingual spray)

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
- **ZOLPIMIST (zolpidem tartrate oral spray)**
 - Non-benzodiazepine sedative-hypnotic indicated for the short-term treatment of insomnia characterized by difficulty with sleep initiation
 - 2019 price increases: \$35.00 to \$140.00 in 3 months
 - Number of current NCSHP utilizers: 6
 - Formulary alternatives include:
 - eszopiclone
 - zolpidem
 - zolpidem extended-release
 - zolpidem sublingual
 - Belsomra (suvorexant)
 - Silenor (doxepin)

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
- **LEVORPHANOL (generic only)**
 - Potent opioid analgesic indicated for the management of moderate to severe pain
 - Average Net Plan Cost = \$4,800 per dispense
 - Number of current NCSHP utilizers: 23
 - Formulary alternatives include:
 - fentanyl transdermal
 - hydromorphone extended-release
 - methadone
 - morphine extended-release
 - Hysingla ER (hydrocodone extended-release)
 - Nucynta ER (tapentadol extended-release)
 - Oxycontin (oxycodone extended-release)

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
- **Fluocinonide 0.1% Cream (generic only)**
 - Class I – Very High potency topical corticosteroid
 - Manufactured by multiple companies
 - Average Net Plan Cost = \$2,100 per dispense
 - Number of current NCSHP utilizers: 730
 - Formulary alternatives include:
 - Augmented betamethasone dipropionate 0.05%
 - Clobetasol propionate 0.05%
 - Diflorasone diacetate 0.05%
 - Halobetasol propionate 0.05%
 - No clinical advantage over the other alternatives

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
- **Hydrocortisone 1% in Absorbase (NDC level only)**
 - Class VII – Lowest potency topical corticosteroid
 - Manufactured by *Solubiomix*
 - Average Net Plan Cost = \$1,500 per dispense
 - Number of current NCSHP utilizers: 38
 - Formulary alternatives include:
 - Hydrocortisone 1%
 - No clinical advantage over the other alternatives

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
- **Benzonatate Capsules 150 MG (NDC level only)**
 - Nonnarcotic antitussive (generic Tessalon Perles)
 - Manufactured by *Solubiomix*
 - Average Net Plan Cost = \$3,400 per dispense
 - Number of current NCSHP utilizers: 20
 - Formulary alternatives include:
 - Other NDC's of benzonatate capsules 150 MG
 - Benzonatate capsules 100 or 200 MG
 - No clinical advantage over the other alternatives

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
- **LAZANDA (fentanyl nasal spray)**
- **ZOLPIMIST (zolpidem tartrate oral spray)**
- **LEVORPHANOL (generic only)**
- **Fluocinonide 0.1% Cream (generic only)**
- **Hydrocortisone 1% in Absorbase (NDC level only)**
- **Benzonatate Capsules 150 MG (NDC level only)**

Formulary Updates – Uptiers

Typically branded medications that have:

- Readily available generic alternatives or,
 - Other preferred formulary alternatives in the therapeutic class
 - Products will move from preferred status to non-preferred (3 or 6)
-
- **BENZACLIN** (clindamycin and benzoyl peroxide) gel 1-5%
 - *Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Acanya (clindamycin-benzoyl peroxide), Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).*
 - Number of current NCSHP utilizers: 10
 - **MIRAPEX ER** (pramipexole extended release) tablets
 - *Preferred options include pramipexole, pramipexole ext-rel, ropinirole, ropinirole ext-rel.*
 - Number of current NCSHP utilizers: 5

Formulary Updates – Uptiers

- **MINASTRIN 24 FE** (Norethindrone Acetate and Ethinyl Estradiol) chewable tablets
 - Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, and Safyral
 - Number of current NCSHP utilizers: 99
- **APTENSIO XR** (methylphenidate HCl ext-rel) capsules
 - Preferred options include amphetamine-dextroamphetamine mixed salts ext-rel, methylphenidate ext-rel, Mydayis (amphetamine-dextroamphetamine mixed salts ext-rel), and Vyvanse (lisdexamfetamine).
 - Number of current NCSHP utilizers: 198
- **QUILLIVANT XR** (methylphenidate HCl ext-rel) suspension
 - Preferred options include amphetamine-dextroamphetamine mixed salts ext-rel, methylphenidate ext-rel, Mydayis (amphetamine-dextroamphetamine mixed salts ext-rel), and Vyvanse (lisdexamfetamine).
 - Number of current NCSHP utilizers: 184

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

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

New-to-Market Block Removals

- Drugs being added to the formulary

DRUG NAME	TIER	DRUG NAME	TIER
Crysvita	6	Arnuity Ellipta	3
Idhifa	6	Mylotarg	6
Radicava	6	Benznidazole	3
Steritalc	3	Mepsevii	6
Prevymis	3	Jynarque	6
Norvir	2	Biktarvy	2
Kevzara	5	Daptomycin	3
Andexxa	3	Qvar Redihaler	2
Daunorubicin	3	Testosterone	1
		Coagadex	6

Formulary Updates – New Drug Additions

STERITALC (talcum)

- Sterile talc - sclerosing agent for PTX/pleural effusion
- Generic sterile talc is on the formulary

NORVIR (ritonavir)

- Powder is indicated for pediatric patients with HIV-1
- New powder formulation

KEVZARA (sarilumab)

- Indicated for the treatment of moderate to severe RA in patients with inadequate response or intolerance to one or more DMARDs.
- New pen administration device; syringes on formulary

DAUNORUBICIN

- Chemotherapy for AML, ALL, CML and Kaposi's sarcoma
- Single source branded medication

ARNUITY ELLIPTA (fluticasone furoate)

- Maintenance treatment of asthma
- New strength (50 mcg)

Utilization Management Policy Review

KEVZARA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Moderately to severely active rheumatoid arthritis (RA)

- A. Authorization of 24 months may be granted for members who have previously received Kevzara or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
- B. Authorization of 24 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
 - 1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
 - 2. Member has an intolerance or contraindication to methotrexate (see Appendix).

CONTINUATION OF THERAPY

- Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Kevzara as evidenced by low disease activity or improvement in signs and symptoms of RA.

Utilization Management Policy Review

Specialty Quantity Limit KEVZARA:

COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Kevzara (sarilumab) 150 mg/1.14 mL single-dose pre-filled syringe	1 pack (2 x 150 mg syringe) per 4 weeks	Rheumatoid arthritis (adult): <ul style="list-style-type: none"> • 200 mg once every two weeks • Reduce dose to 150 mg once every two weeks for management of neutropenia, thrombocytopenia and elevated liver enzymes
Kevzara (sarilumab) 150 mg/1.14 mL single-dose pre-filled pen	1 pack (2 x 150 mg pen) per 4 weeks	
Kevzara (sarilumab) 200 mg/1.14 mL single-dose pre-filled syringe	1 pack (2 x 200 mg syringe) per 4 weeks	
Kevzara (sarilumab) 200 mg/1.14 mL single-dose pre-filled pen	1 pack (2 x 200 mg pen) per 4 weeks	

Formulary Updates – New Drug Additions

JYNARQUE (tolvaptan)

- Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)
- Same active ingredient as formulary product, SAMSCA; different indication

DAPTOMYCIN

- Lipopeptide antibiotic bactericidal against Gram positives
- New strength not a new formulation

QVAR REDHALER (beclomethasone dipropionate HFA)

- Corticosteroid for maintenance treatment of asthma
- Redihaler is a new breath actuated inhaler device

TESTOSTERONE GEL 1% (50 MG)

- Replacement therapy for hypogonadism
- Additional generic testosterone strength

Utilization Management Policy Review

JYNARQUE Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

- Authorization of 12 months may be granted for patients who are initiating Jynarque therapy for the treatment of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

CONTINUATION OF THERAPY

- Authorization of 12 months may be granted to patients who have demonstrated a beneficial response to Jynarque therapy (e.g., slowed kidney function decline).

Utilization Management Policy Review

Corticosteroid Oral Inhalation Quantity Limit:

EFFECTED MEDICATIONS

- Aerospan, Alvesco, Armonair Respiclick, Arnuity Ellipta, Asmanex HFA, Asmanex Twisthaler, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler, Pulmicort Respules, Qvar, **Qvar Redihaler**

QUANTITY LIMITS

Pulmicort Respules 0.5mg	nebulization of 1-2 respules (2-4mL) daily	2 respules (1mg)	30 respules (2mL each) per carton	2 packages (60 respules x 2mL) / 25 days 6 packages (180 respules x 2mL) / 75 days
Pulmicort Respules 1mg	nebulization of 1 respule (2mL) daily	1 respule (1mg)	30 respules (2mL each) per carton	1 package (30 respules x 2mL) / 25 days 3 packages (90 respules x 2mL) / 75 days
QVAR 40mcg**	1-3 inhalations twice daily	6 inhalations**	120 inhalations per 8.7gm canister	2 packages (8.7gm each) / 25 days 6 packages (8.7gm each) / 75 days
QVAR 80mcg	1-4 inhalations twice daily	8 inhalations (640mcg)	120 inhalations per 8.7gm canister	2 packages (8.7gm each) / 25 days 6 packages (8.7gm each) / 75 days
QVAR RediHaler 40mcg**	1-3 inhalations twice daily	6 inhalations**	120 inhalations per 10.6gm canister	2 packages (10.6gm each) / 25 days 6 packages (10.6gm each) / 75 days
QVAR RediHaler 80mcg	1-4 inhalations twice daily	8 inhalations (640mcg)	120 inhalations per 10.6gm canister	2 packages (10.6gm each) / 25 days 6 packages (10.6gm each) / 75 days

*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.
 *The limit criteria apply to both brand and generic, if available.
 **Utilize higher strength available.

LIMIT CRITERIA

Medication**	Starting Dose	Maximum** Daily Dose	Package Size	1 Month Limit* 3 Months Limit*
Aerospan 80mcg	1-4 inhalations twice daily	8 inhalations (640mcg)	120 inhalations per 8.9gm canister	2 packages (8.9gm each) / 25 days 6 packages (8.9gm each) / 75 days
Alvesco 80mcg**	1-3 inhalations twice daily	6 inhalations**	60 inhalations per 6.1gm canister	3 packages (6.1gm each) / 25 days 9 packages (6.1gm each) / 75 days
Alvesco 160 mcg	1-2 inhalations twice daily	4 inhalations (640mcg)	60 inhalations per 6.1gm canister	2 packages (6.1gm each) / 25 days 6 packages (6.1gm each) / 75 days
Armonair Respiclick 55mcg**	1 inhalation twice daily	2 inhalations**	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Armonair Respiclick 113mcg**	1 inhalation twice daily	2 inhalations**	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Armonair Respiclick 232mcg	1 inhalation twice daily	2 inhalations (464mcg)	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Arnuity Ellipta 50	1 inhalation once daily	1 inhalation	30 blisters per inhaler	1 package (30 blisters) / 25 days 3 packages (30 blisters each) / 75 days
Arnuity Ellipta 100**	1 inhalation once daily	1 inhalation**	30 blisters per inhaler	1 package (30 blisters) / 25 days 3 packages (30 blisters each) / 75 days
Arnuity Ellipta 200	1 inhalation once daily	1 inhalation (200mcg)	30 blisters per inhaler	1 package (30 blisters) / 25 days 3 packages (30 blisters each) / 75 days
Asmanex HFA 100mcg**	2 inhalations twice daily	4 inhalations**	120 inhalations per 13gm canister	1 package / 25 days 3 packages / 75 days
Asmanex HFA 200mcg	2 inhalations twice daily	4 inhalations (800mcg)	120 inhalations per 13gm canister	1 package / 25 days 3 packages / 75 days
Asmanex Twisthaler 110mcg**	1 inhalation once daily	2 inhalations**	30 inhalation units per package	2 packages / 25 days 6 packages / 75 days
Asmanex Twisthaler 220mcg	1-2 inhalations once-twice daily	4 inhalations (880mcg)	30 inhalation units per package 60 inhalation units per package 120 inhalation units per package	4 packages / 25 days 12 packages / 75 days 2 packages / 25 days 6 packages / 75 days 1 package / 25 days 3 packages / 75 days
Flovent Diskus 50mcg**	1-3 inhalations twice daily	6 inhalations**	60 blisters per device	3 packages (60 blisters each) / 25 days 9 packages (60 blisters each) / 75 days
Flovent Diskus 100mcg**	1-4 inhalations twice daily	8 inhalations**	60 blisters per device	4 packages (60 blisters each) / 25 days 12 packages (60 blisters each) / 75 days
Flovent Diskus 250mcg	1-4 inhalations twice daily	8 inhalations (2000mcg)	60 blisters per device	4 packages (60 blisters each) / 25 days 12 packages (60 blisters each) / 75 days
Flovent HFA 44mcg**	2-4 inhalations twice daily	8 inhalations**	120 inhalations per 10.6gm canister	2 packages (10.6gm each) / 25 days 6 packages (10.6gm each) / 75 days
Flovent HFA 110mcg**	1-3 inhalations twice daily	6 inhalations**	120 inhalations per 12gm canister	2 packages (12gm each) / 25 days 6 packages (12gm each) / 75 days
Flovent HFA 220mcg	1-4 inhalations twice daily	8 inhalations (1760mcg)	120 inhalations per 12gm canister	2 packages (12gm each) / 25 days 6 packages (12gm each) / 75 days
Pulmicort Flexhaler 90mcg**	2-3 inhalations twice daily	6 inhalations**	60 inhalations per device	3 packages / 25 days 9 packages / 75 days
Pulmicort Flexhaler 180mcg	1-4 inhalations twice daily	8 inhalations (1440mcg)	120 inhalations per device	2 packages / 25 days 6 packages / 75 days
Pulmicort Respules 0.25mg**	nebulization of 1-2 respules (2-4mL) daily	3 respules**	30 respules (2mL each) per carton	3 packages (90 respules x 2mL) / 25 days 9 packages (270 respules x 2mL) / 75 days

Formulary Updates – New Drug Additions

CRYSVITA (burosumab-twza)

- Indication:
 - X-linked hypophosphatemia (XLH)
 - Body does not retain enough phosphorus which can lead to osteomalacia
- MOA:
 - Fibroblast growth factor 23 blocking antibody
 - Binds to and inhibits the biological activity of FGF23, restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy-vitamin D, which plays a role in phosphate absorption in the small intestines
- Place in Therapy:
 - First Approved Therapy for XLH in the U.S.
 - Only Treatment that Targets the Underlying Cause of this Rare, Hereditary, Lifelong Disease
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

CRYSVITA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

X-linked Hypophosphatemia

Indefinite authorization may be granted for treatment of X-linked hypophosphatemia when either of the following criteria are met:

- A. Genetic testing was conducted to confirm a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation in the patient or a directly related family member with appropriate X-linked inheritance.
- B. Serum fibroblast growth factor 23 (FGF23) level is greater than 30 pg/ml.

Formulary Updates – New Drug Additions

IDHIFA (enasidenib)

- Indication:
 - treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
- MOA:
 - Small molecule inhibitor of the isocitrate dehydrogenase 2 (IDH2) enzyme
 - IDH2 converts isocitrate to alpha-ketoglutarate (α -KG), a substrate for enzymes essential to gene expression and myeloid differentiation
 - Mutated IDH2 converts α -KG to 2-hydroxyglutarate (2-HG), an oncometabolite that leads to a block on myeloid differentiation and results in myeloblast proliferation
 - Idhifa blocks the conversion of α -KG to 2-HG which induced myeloid differentiation
- Place in Therapy:
 - the First Oral Targeted Therapy for Adult Patients with Relapsed/Refractory Acute Myeloid Leukemia and an IDH2 Mutation
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

IDHIFA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

- Authorization of 12 months may be granted for the treatment of relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

Formulary Updates – New Drug Additions

RADICAVA (edaravone)

- Indication:
 - Treatment of amyotrophic lateral sclerosis (ALS)
- MOA:
 - Unknown
 - Helps to control excessive oxidative stress in the body
- Place in Therapy:
 - First new ALS therapy in 22 years
 - Shown to slow the decline of physical function based on the ALS Functional Rating Scale-Revised (ALSFRS-R)
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

RADICAVA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of ALS when all of the following criteria are met:

- A. Diagnosis of definite or probable ALS
- B. Duration of ALS is 2 years or less
- C. Functional ability is retained for most activities of daily living (ADLs)
- D. Ventilatory support, noninvasive or invasive, is not required

CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members continuing with Radicava therapy when the following criteria are met:

- A. Diagnosis of definite or probable ALS
- B. There is a clinical benefit from Radicava therapy such as stabilization of functional ability and maintenance of ADLs
- C. Invasive ventilation is not required

Formulary Updates – New Drug Additions

PREVYMIS (letermovir)

- Indication:
 - prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
- MOA:
 - Inhibits the CMV DNA terminase complex which is required for viral DNA processing and packaging
- Place in Therapy:
 - This is the first new CMV therapy to come along in 15 years
 - In the pivotal Phase 3 clinical trial supporting approval, significantly fewer patients in the PREVYMIS group (38%, n=122/325) compared to the placebo group (61%, n=103/170) developed clinically significant CMV infection, discontinued treatment or had missing data through Week 24 post-HSCT [treatment difference: -23.5 (95% confidence interval -32.5 to -14.6), (p<0.0001)], the primary efficacy endpoint.
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Formulary Updates – New Drug Additions

ANDEXXA (coagulation factor Xa [recombinant] inactivated-zhzo)

- Indication:
 - Treatment for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.
- MOA:
 - Binding and sequestering the FXa inhibitors, rivaroxaban and apixaban
 - Binds and inhibits the activity of Tissue Factor Pathway Inhibitor (TFPI) which can increase tissue factor-initiated thrombin generation.
- Place in Therapy:
 - First and only antidote for the reversal of Factor Xa Inhibitors, rivaroxaban and apixaban
- Proposed Tier Placement:
 - Tier 3 – Nonpreferred Brand

Formulary Updates – New Drug Additions

MYLOTARG (gemtuzumab ozogamicin)

- Indication:
 - Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults
 - Treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older
- MOA:
 - CD33-directed antibody-drug conjugate
 - Binding of the ADC to CD33-expressing tumor cells causes double-strand DNA breaks, subsequently inducing cell cycle arrest and apoptotic cell death
- Place in Therapy:
 - First and only AML therapy that targets CD33, an antigen expressed on AML cells in up to 90% of patients
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

MYLOTARG Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)/ Acute Promyelocytic Leukemia (APL)

- Authorization of 12 months may be granted for the treatment of AML/APL if the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen.

Formulary Updates – New Drug Additions

BENZNIDAZOLE

- Indication:
 - Treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi* in pediatric patients 2 to 12 years of age
- MOA:
 - Nitroimidazole antimicrobial
 - Inhibits the synthesis of DNA, RNA, and proteins within the *T. cruzi* parasite
- Place in Therapy:
 - First treatment approved in the United States for the treatment of Chagas disease
- Proposed Tier Placement:
 - Tier 3 – Nonpreferred Brand

Formulary Updates – New Drug Additions

MEPSEVII (vestronidase alfa-vjvk)

- Indication:
 - Treatment of pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)
 - Lysosomal disorder characterized by the deficiency of GUS that results in GAG accumulation in cells throughout the body leading to multisystem tissue and organ damage
- MOA:
 - Recombinant human lysosomal beta glucuronidase
 - Intended to provide exogenous GUS enzyme for uptake into cellular lysosomes via mannose-6 phosphate residues
 - Helps catabolize the GAGs that accumulate in the tissues of patients with MPS VII
- Place in Therapy:
 - The first and only enzyme replacement therapy for MPS VII (Sly syndrome)
 - Demonstrated improvement and stabilization across multiple measures such as the 6-minute walk test (6MWT)²
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

MEPSEVII Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

- Indefinite authorization may be granted for treatment of MPS VII (Sly syndrome) when the diagnosis of MPS VII was confirmed by enzyme assay demonstrating a deficiency of beta-glucuronidase enzyme activity or by genetic testing.

Formulary Updates – New Drug Additions

BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide)

- Indication:
 - Complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen for ≥3 months with no history of treatment failure and no known resistance to any component of BIKTARVY
- MOA:
 - Dual-nucleoside analog reverse transcriptase inhibitors (NRTI) backbone of emtricitabine & tenofovir (FTC/TAF) with bictegravir (BIC), a novel and unboosted integrase strand transferase (INSTI)
- Place in Therapy:
 - Complete HIV-1 treatment that combines 3 different medicines into 1 small pill, taken once a day with or without food
 - High barrier to resistance through Week 48 of clinical trials
- Proposed Tier Placement:
 - Tier 2 – Preferred Brand

Formulary Updates – New Drug Additions

COAGADEX (coagulation factor X [Human])

- Indication:
 - Hereditary factor X deficiency in adults and children (aged 12 years and above) for:
 - On-demand treatment and control of bleeding episodes
 - Perioperative management of bleeding in patients with mild hereditary factor X deficiency
- MOA:
 - Temporarily replaces the missing Factor X needed for effective hemostasis
- Place in Therapy:
 - First and only treatment specifically for hereditary factor X deficiency
 - Contains more than 94% factor X
- Proposed Tier Placement:
 - Tier 6 – Nonpreferred Specialty

Utilization Management Policy Review

COAGADEX Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Hereditary Factor X Deficiency

- A. Indefinite authorization may be granted for on-demand treatment and control of bleeding episodes.
- B. Authorization 1 month may be granted for perioperative management of bleeding in members with mild disease (i.e., baseline Factor X assay level $\geq 5\%$).

Formulary Updates – New Drug Additions

New-to-Market Block Removals

- Drugs being added to the formulary

DRUG NAME	TIER	DRUG NAME	TIER
Crysvita	6	Arnuity Ellipta	3
Idhifa	6	Mylotarg	6
Radicava	6	Benznidazole	3
Steritalc	3	Mepsevii	6
Prevymis	3	Jynarque	6
Norvir	2	Biktarvy	2
Kevzara	5	Daptomycin	3
Andexxa	3	Qvar Redihaler	2
Daunorubicin	3	Testosterone	1
		Coagadex	6

Utilization Management Policy Review

New Policies Under Consideration

- **CVS Standard Criteria**

- NUEDEXTA Initial Prior Authorization
- Topical NSAIDs Initial Prior Authorization with Quantity Limit
- Topical Vitamin D Analogs Initial Prior Authorization

- **NCSHP Custom Criteria**

- CHENODAL Initial Prior Authorization
- NAPRELAN Initial Prior Authorization
- THIOLA Initial Prior Authorization

Utilization Management Policy Review

NUEDEXTA Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

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

- The patient has a diagnosis of pseudobulbar affect (PBA)

Utilization Management Policy Review

Topical NSAIDs Initial Prior Authorization w/ Quantity Limit:

CRITERIA FOR INITIAL APPROVAL

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

- The patient has osteoarthritis pain of the knee(s)

AND

- Treatment with diclofenac topical solution is necessary due to intolerance or a contraindication to oral nonsteroidal anti-inflammatory drugs (NSAIDs)

*QUANTITY LIMIT		
This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.		
Medication	4 Weeks Limit*	12 Weeks Limit*
Pennsaid (diclofenac sodium top soln 2%)	2 bottles (112gm each) 224gm / 21 days	6 bottles (112gm each) 672gm / 63 days
diclofenac sodium top soln 1.5%	3 bottles (150mL each) 450mL / 21 days	9 bottles (150mL each) 1350mL / 63 days
Klofensaid II (diclofenac sodium top soln 1.5%)	3 bottles (150mL each) 450mL / 21 days	9 bottles (150mL each) 1350mL / 63 days
* The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.		

Utilization Management Policy Review

Topical Vitamin D Analogs Initial Prior Authorization:

AFFECTED MEDICATIONS

- Calcipotriene topical scalp solution, Calcitrene, Dovonex, Enstilar, Sorilux, Taclonex, Vectical

CRITERIA FOR INITIAL APPROVAL

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

- The requested drug is being prescribed for the treatment of psoriasis.

AND

- The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (e.g., betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide).

Utilization Management Policy Review

CHENODAL Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

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

- The requested drug is being used for the treatment of radiolucent stones in a well-opacifying gallbladder

AND

- The patient had an increased surgical risk due to systemic disease or age, whereby they are not a candidate for selective surgery

OR

- The requested drug is being used for the treatment of cerebrotendinous xanthomatosis (CTX) disorder that has been confirmed by cholestanol testing

Utilization Management Policy Review

NAPRELAN Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

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

- The patient is 18 years of age or older

AND

- The requested drug is being prescribed for the relief of the signs and symptoms of any of the following:
 - A. Rheumatoid Arthritis
 - B. Osteoarthritis
 - C. Ankylosing Spondylitis
 - D. Gouty Arthritis
 - E. Mild to Moderate Pain

AND

- The patient had an inadequate treatment response to BOTH immediate-release and delayed-release naproxen

Utilization Management Policy Review

THIOLA Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

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

- The requested drug is being used for the prevention of cystine (kidney) stone formation who has severe homozygous cystinuria with urinary cystine greater than 500 milligrams per day

AND

- The patient is resistant to treatment with the conservative measures of high fluid intake, alkali and diet modification

AND

- The patient had an adverse reactions to d-penicillamine

Summary

If approved, the following formulary changes will go into effect 10/1/2018 and include the following:

- **Drug Exclusions**

- Lazanda, Zolpimist, levorphanol, hydrocortisone 1% in Absorbase, Fluocinonide 0.1% Cream, & Benzonatate Capsules 150 MG

- **Uptiers**

- Benzaclin, Mirapex ER, Minastrin 24 Fe chew, Aptensio XR, & Quillivant XR

- **Downtiers**

- None

- **New Drug Additions**

- Crysvida, Idhifa, Radicava, Steritalc, Prevymis, Norvir, Kevzara, Andexxa, Daunorubicin, Arnuity Ellipta, Mylotarg, Benznidazole, Mepsevii, Jynarque, Biktarvy, Daptomycin, Qvar Redihaler, testosterone gel 1%, & Coagadex

- **Utilization Management**

- Coagadex, Corticosteroid Oral Inhalation, Crysvida, Idhifa, Jynarque, Kevzara, Mepsevii, Mylotarg, Radicava, Nuedexta, Topical NSAIDs, Topical Vitamin D Analogs, Chenodal, Naprelan, & Thiola,



Next meeting: October 23, 2018



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



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