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

Formulary and Program Updates Effective 8/1/18

Pharmacy & Therapeutics Committee Meeting

May 22, 2018
6:30 – 8:00 PM

Role Call

VOTING MEMBERS

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

NON-VOTING MEMBERS

- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones
- Lucy Barreto, DDS, MHA
- 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 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.

Recent Plan Formulary Decisions

- CVS Enhanced MME-based Opioid went into effect 3/1/2018
- Formulary changes and additions that were approved at the last meeting in February went into effect 5/1/2018
- Removed the following Prior Authorizations:
  - Buprenorphine
  - Buprenorphine/Naloxone
  - NOXAFIL®
  - VFEND® (effective 6/1/2018)
  - PPI Step Therapy (effective 6/1/2018)
- Adopted the following new Prior Authorizations/Quantity Limit/Step Therapy criteria:
  - ACTICLATE® Initial Step Therapy; Post Step Therapy Prior Authorization
  - ZEGERID® Initial Prior Authorization

Formulary Updates – Effective 8/1/2018

CVS Caremark's Quarterly Formulary Update

- Product Exclusions
- Tier Changes
- New Drug Additions

Presented by:

- Heather Renee Jarnigan, RPh, 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

  - **SYNERDERM®** Emulsion
    - Topical product used to manage and relieve burning and itching associated with dermatoses
    - Part of group of dermatological products that receive approval via FDA process section 510k of the Food, Drug and Cosmetic Act
    - Ingredients: Deionized water, copolymer, vegetable oils from African Palms, silver nanoparticles (as a preservative)
    - Preferred options are generic desonide and hydrocortisone

Formulary Updates – Product Exclusions

- Other 510K Products
  - **NEUTRASAL®**
    - Artificial Saliva substitute
    - Supersaturated calcium phosphate rinse
    - Alternatives include pilocarpine, cevimeline, xanthum gum mouthwash, toothpaste with 4% betaine, oxygenated glycerol tiester spray (Saliveze), biotene dry mouth oral rinse, xylitol-based gum, other salivary substitutes: mucin, carboxymethyl cellulose, hydroxyethyl cellulose, water-glycerin, and glycerate polymer
  - **SALIVAMAX™**
    - Artificial Saliva substitute
    - Ingredients include calcium chloride, sodium bicarbonate, sodium chloride, sodium phosphates (dibas/monob)
    - Alternatives include pilocarpine, cevimeline, xanthum gum mouthwash, toothpaste with 4% betaine, oxygenated glycerol tiester spray (Saliveze), biotene dry mouth oral rinse, xylitol-based gum, other salivary substitutes: mucin, carboxymethyl cellulose, hydroxyethyl cellulose, water-glycerin, and glycerate polymer

Formulary Updates – Product Exclusions

- Other 510K Products
  - **HPR PLUS™**
    - Emoillient Foam, Cream and Kit Formulations
    - Ingredients: Water, Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Propylene Glycol, Dicetyl Phosphate, Theobroma Grandiorum Seed Butter, Petrolatum, Dimethicone, Steareth-10, Ceteareth-10 Phosphate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Tocopheryl Acetate, Methylparaben, Disodium EDTA, Propylparaben, Sodium Hyaluronate and Sodium Hydroxide. HPRplusTM Emollient Foam also contains Hydrouorocarbon 134a (propellant).
    - Alternatives:
      - For atopic dermatitis: emollients considered step 1 (e.g. petroleum jelly, CeraVe, Amlactin, Carmol 20, Mederma, Lac-Hydrin, Lubriderm, Aveeno, Cetaphil, Aquaphor, Eletone); for flares, consider topical steroids (e.g. desonide 0.05%, fluocinolone 0.01%, betamethasone 0.1%, Cutivate 0.05%; 2nd or 3rd line for anti-inflammatory conditions: tacrolimus ointment 0.03% or 0.1% or pimecrolimus cream 1%.
      - For contact dermatitis: topical steroids recommended first-line: triamcinolone 1%, clobetasol 0.05%; second-line: tacrolimus 0.1% ointment
      - For burns: 1% silver sulfadiazene (Silvadene, Flamazine, Thermazene, SSD); other products: duoderm, biobrane, mepitel, repithel, honey dressing, aloe vera; non-silver antimicrobial topicals for partial-thickness burns: bacitracin, chlorhexidine, sulfamylon, nystatin; silver-impregnanted dressing options: acticoat, aquacel Ag, askina calgitrol Ag, Mepilex Ag

Formulary Updates – Product Exclusions

- Standard Control and Advanced Control Specialty
  - Antilipemic Agent, PCSK9 Inhibitor

  - **PRALUENT®** (alirocumab) injection
    - Monoclonal antibody used as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C
    - Preferred option is REPATHA® (evolocumab)
    - 42 Plan members are current utilizers whose prior authorizations will be auto-approved for REPATHA® to prevent repetition of the PA process

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)

- **ALINIA®** (nitazoxanide) tablets and suspension
  - *Preferred option is generic tinidazole (for Giardia lamblia)*
- **COARTEM®** (artemether/lumefantrine) tablets
  - *Preferred options include generics atovaquone-proguanil, chloroquine, and mefloquine.*
- **SIVEXTRO®** (tedizolid) capsules
  - *Preferred option is generic linezolid*
- **NAMENDA XR®** (memantine) capsules
  - *Preferred option is generic memantine*

Formulary Updates – Uptiers

- **AZILECT®** (rasagiline) tablets
  - *Preferred options include generics rasagiline and selegiline*
- **BEYEZ®** (drospirenone; ethinyl estradiol; levomefolate) tablets
  - *Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, Lo Loestrin Fe (norethindrone acetate/EE 1/10 and EE 10 and iron), Minastrin 24 Fe (norethindrone acetate/EE 1/20 and iron chewable), and Safyral (drospirenone/EE/levomefolate 3/30 and levomefolate)*
- **LOTRONEX®** (alosetron) tablets
  - *Preferred options include alosetron and Viberzi (eluxadoline)*
- **VOLTAREN®** (diclofenac) gel
  - *Preferred options include generics diclofenac sodium, diclofenac sodium gel 1%, diclofenac sodium solution, meloxicam, and naproxen.*

Formulary Updates – Uptiers

- **FLUOXETINE 60 mg (Brand)** tablets
  - *Preferred options include generics include citalopram, escitalopram, fluoxetine, paroxetine HCl, paroxetine HCl ext-rel, sertraline, Trintellix (vortioxetine), and Viibryd (vilazodone)*
- **FURADANTIN®** (nitrofurantoin) suspension
  - *Preferred options include generic nitrofurantoin*
- **PARLODEL®** (bromocriptine) tablets
  - *Preferred options include generics or preferred brands Mirapex ER, Neupro.*

Formulary Updates – Downtiers

- Typically branded medications:
  - Moved to a preferred product position (tier 2 or 5)

- **ORFADIN®** (nitisinone) capsules and suspension
- **MYDAYIS®** (amphetamine/dextroamphetamine)

BOLDED medications indicate specialty drug designation

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
  - 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
  - New formulations or strengths of drugs already on the formulary
  - SSB = single sourced branded medication

DRUG NAME	TIER	DRUG NAME	TIER
Betamethsone Sod Inj (SSB)	3	Mitomycin	6
Citranatal Medley	2	Mydayis	2
Clenpiq	3	Palonosetron (SSB)	3
Daliresp	2	Vancomycin/NaCL 1.5mg/300 ml Inj	3
Esmolol IV Sol (SSB)	3	Vyvanse Chewable	2
Hyperrab	3	Xhance (Fluticasone Propionate Nasal)(SSB)	3
Imbruvica	6	Zenpep	2
Makena	6		

Formulary Updates – New Drug Additions

- New Molecular Entities

DRUG NAME	TIER
Imfinzi (durvalumab)	6
Odactra (House Dust Mite Allergen)	3
Ozempic (semaglutide)	2
Symdeko (tezacaftor/ivacaftor)	6
Trogarzo (ibalizumab)	6
Xermelo (telotristat ethyl)	6

- New Drugs from Previous Meeting
  - **CALQUENCE®** (acalabrutinib)
  - **VERZENIO®** (albemaciclib)

CALQUENCE®

(acalabrutinib) capsules, for oral use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	Imbruvica (ibrutinib) (tier 6)
FDA Approval	October 31, 2017, Orphan Drug and Breakthrough Therapy designations
Therapeutic Class	Bruton's tyrosine kinase (BTK) inhibitor
Indications and Usage	Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
Dosing	***Forms & Strengths:*** 100 mg capsules ***Administration:*** 100 mg orally every 12 hours; swallow whole, do not break; may take with or without food ***Adjustments:*** None
Safety	***Contraindications:*** None ***Warnings:*** Hemorrhage, infection, cytopenias, second primary malignancies, atrial fibrillation and flutter ***Adverse Reactions:*** (≥ 20%): decreased hemoglobin, decreased platelets, headache, decreased neutrophils, diarrhea, fatigue, myalgia, and bruising
Key Points	Patients had an overall response rate of 81%, with a complete response rate of 40% and a partial response rate of 41%
Treatment Guidelines	The 2017 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for MCL recommend Calquence, Imbruvica (ibruvica), chemotherapy regimens ± Rituxan (rituximab), Velcade (bortezomib) ± Rituxan, Revlimid (lenalidomide) ±, Venclexta (venetoclax), radiation therapy, or enrollment in a clinical trial for patients requiring second-line therapy.
Place in Therapy	Calquence is the second BTK inhibitor FDA-approved to treat adult patients with MCL who have received at least one prior therapy.

SPECIALTY GUIDELINE MANAGEMENT

CALQUENCE (acalabrutinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Calquence is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Mantle cell lymphoma
Authorization of 12 months may be granted for the treatment of mantle cell lymphoma when the member has received at least one prior therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VERZENIO®

(abemaciclib) tablets, for oral use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	Ibrance (palbociclib) or Kisqali (ribociclib)
FDA Approval	October 31, 2017, Breakthrough Therapy and Priority Review designations
Therapeutic Class	Cyclin-dependent kinase (CDK) inhibitor
Indications and Usage	Indicated in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy & as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
Dosing	***Forms & Strengths:*** Tablets: 50 mg, 100 mg, 150 mg, and 200 mg ***Administration:*** take orally with or without food; Recommended starting dose in combination with fulvestrant: 150 mg twice daily, monotherapy: 200 mg twice daily ***Adjustments:*** Dosing interruption and/or dose reductions may be required based on individual safety and tolerability; advise not to breastfeed
Safety	***Contraindications:*** None ***Warnings:*** Diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, and embryo-fetal toxicity ***Adverse Reactions:*** (≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, and thrombocytopenia.
Key Points	Verzenio is the only CDK4 & 6 inhibitor approved with a continuous dosing schedule
Treatment Guidelines	The 2017 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for breast cancer recommend Ibrance or Kisqali plus Femera (letrozole) as a first-line option for treating HR-positive, HER2-negative metastatic breast cancer. Ibrance plus Faslodex (fulvestrant) may be considered in women with HR-positive, HER@-negative disease that has progressed on prior endocrine therapy.
Place in Therapy	Verzenio provides a new treatment option for women with HR+, HER2- advanced breast cancer

SPECIALTY GUIDELINE MANAGEMENT

VERZENIO (abemaciclib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Verzenio is indicated:

A. In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
B. As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer when any of the following criteria are met:

A. Verzenio will be used in combination with fulvestrant for a member who has experienced disease progression following endocrine therapy.
B. Verzenio will be used as monotherapy for a member who has experienced disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

XERMELO®

(telotristat ethyl) tablets, for oral use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	None
FDA Approval	February 28, 2017 (fast track designation, priority review, orphan drug status)
Therapeutic Class	Tryptophan Hydroxylase Inhibitor
Indications and Usage	Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.
Dosing	***Forms & Strengths:*** 250 mg Tablets ***Administration:*** 250 mg three times daily; Take with food; administer short-acting octreotide at least 30 minutes after administering Xermelo. ***Adjustments:*** None
Safety	***Contraindications:*** None ***Warnings:*** Xermelo reduces bowel movement frequency; monitor patients for constipation and/or severe persistent or worsening abdominal pain. Discontinue Xermelo if severe constipation or abdominal pain develops. ***Adverse Reactions:*** (≥ 5%): nausea, headache, increased GGT, depression, flatulence, decreased appetite, peripheral edema, and pyrexia.
Key Points	The first and only oral treatment for carcinoid syndrome diarrhea.
Treatment Guidelines	The main goals of carcinoid tumor management are symptom control, biochemical control (that is, normalizing the 5-hiaa level), objective tumor control, and quality-of-life improvement. Different strategies are used to manage functioning and non-functioning carcinoid tumors. Somatostatin analogues for symptom control, frequent debulking, and better management of cardiac complications have improved survival rates.
Place in Therapy	Xermelo will provide patients whose carcinoid syndrome diarrhea is not adequately controlled with another treatment option.

SPECIALTY GUIDELINE MANAGEMENT

XERMELO (telotristat ethyl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Xermelo is indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Carcinoid syndrome diarrhea
Authorization of 12 months may be granted for the treatment of carcinoid syndrome diarrhea when all of the following criteria are met:

1. Member has had an inadequate response to somatostatin analog (SSA) therapy.
2. Xermelo will be used in combination with SSA therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IMFINZI®

(durvalumab) injection, for intravenous use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	None
FDA Approval	May 1, 2017 (urothelial carcinoma) & February 16, 2018 (NSCLC)
Therapeutic Class	Programmed death-ligand (PD-L1) blocking antibody
Indications and Usage	Indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy AND unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
Dosing	***Forms & Strengths:*** 500 mg/10 mL & 120 mg/2.4 mL (50 mg/mL) solution in a single-dose vial ***Administration:*** 10 mg/kg every 2 weeks for both indications. ***Adjustments:*** None
Safety	***Contraindications:*** None ***Warnings:*** Immune-mediated pneumonitis, hepatitis, colitis, endocrinopathies, nephritis, & dermatologic reactions; Infection; Infusion-related reactions; Embryo-Fetal Toxicity ***Adverse Reactions:*** (≥ 15% of patient with urothelial carcinoma): fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral edema, and urinary tract infection. (≥ 20% of patient with unresectable, Stage III NSCLC): cough, fatigue, pneumonitis/radiation pneumonitis, upper respiratory tract infections, dyspnea, and rash.
Key Points	The first and only approved treatment following concurrent chemoradiation therapy (CRT) for patients with unresectable stage III non-small cell lung cancer. Imfinzi is also under investigation in the Phase III DANUBE trial as 1st- line treatment in urothelial carcinoma as monotherapy and in combination with tremelimumab.
Treatment Guidelines	Unresectable, Stage III NSCLC: CRT is treatment of choice followed by sequential chemotherapy. Immunotherapy can then be used if disease has not progressed. Urothelial carcinoma: Radiation therapy, chemotherapy, transurethral resection for bladder tumor, radical cystectomy, intravesical treatment
Place in Therapy	Provide another treatment option for urothelial carcinoma patients who have disease progression during or following chemotherapy & provides a FDA-approved treatment option for NSCLC patients following chemoradiation.

SPECIALTY GUIDELINE MANAGEMENT

IMFINZI (durvalumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

A. Locally advanced or metastatic urothelial carcinoma in patients with disease progression during or following platinum-containing chemotherapy or with disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
B. Unresectable, stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Urothelial carcinoma

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma when any of the following criteria is met:

1. Member experienced disease progression during or following platinum-containing chemotherapy.
2. Member experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

B. Non-small cell lung cancer

Authorization of up to 12 months may be granted for treatment of unresectable, stage III NSCLC following concurrent platinum-based chemotherapy and radiation therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

OZEMPIC®

(semaglutide) injection, for subcutaneous use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 2 – Preferred Brand
Formulary Alternatives	Trulicity (dulaglutide), Victoza (liraglutide)
FDA Approval	December 5, 2017
Therapeutic Class	Incretin Mimetic; Glucagon-Like Peptide 1 (GLP-1) Receptor Agonist
Indications and Usage	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dosing	***Forms & Strengths:*** 2 mg/1.5 mL available in single patient use pen that delivers 0.25 or 0.5 mg per injection & a single patient use pen that delivers 1 mg per injection ***Administration:*** Start at 0.25 mg once weekly. After 4 weeks, increase the dose to 0.5 mg once weekly. If after at least 4 weeks additional glycemic control is needed, increase to 1 mg once weekly. Administer once weekly at any time of day, with or without meals, subcutaneously in the abdomen, thigh, or upper arm. If dose is missed administer within 5 days of missed dose. ***Adjustments:*** Discontinue OZEMPIC® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.
Safety	***Contraindications:*** Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 or known hypersensitivity to Ozempic or any of the product components ***Warnings:*** Risk of Thyroid C-Cell Tumors, Pancreatitis, Diabetic Retinopathy Complications, Hypoglycemia, Acute Kidney Injury, Hypersensitivity Reactions, Macrovascular outcomes, Do not share pens. ***Adverse Reactions:*** (≥ 5%): nausea, vomiting, diarrhea, abdominal pain and constipation
Key Points	Ozempic was studied head-to-head vs Trulicity (dulaglutide), Januvia (sitagliptin), and Bydureon (exenatide). Ozempic was also studied in a cardiovascular outcome trial vs placebo or standard of care.
Treatment Guidelines	Diabetes: lifestyle modification, then depending on entry A1c levels monotherapy with metformin, dual therapy with metformin and another 1st-line agent (GLP-1, SGLT, DPP, etc), triple therapy with metformin + 1st-line agent + 2nd-line agent, add insulin and intensify from there.
Place in Therapy	Provide another preferred glucagon-like peptide 1 (GLP-1) receptor agonist option for patients.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**GLP-1 AGONIST**
BRAND NAME (generic)	**OZEMPIC (semaglutide)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS
Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Ozempic is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans
- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis
- Ozempic is not a substitute for insulin. OZEMPIC is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

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

- The patient has been receiving GLP-1 Agonist therapy for at least 3 months and has demonstrated a reduction in A1c (hemoglobin A1c) since starting GLP-1 Agonist therapy. [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Tanzeum, Trulicity, Victoza]
  OR
- The patient has a diagnosis of type 2 diabetes mellitus
  AND
  - The patient has experienced an inadequate treatment response, contraindication, or intolerance to metformin
    OR
  - The patient requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater

TROGARZO®

(ibalizumab-uiyk) injection, for intravenous use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	None.
FDA Approval	March 6, 2018 (fast track, priority review, breakthrough therapy, orphan drug)
Therapeutic Class	CD4-directed post-attachment HIV-1 inhibitor
Indications and Usage	Indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.
Dosing	***Forms & Strengths:*** 200 mg/1.33 mL injection in a single-dose vial ***Administration:*** intravenously (IV) as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection. ***Adjustments:*** Women infected with HIV should be instructed not to breastfeed due to the potential for HIV transmission
Safety	***Contraindications:*** none ***Warnings:*** Immune Reconstitution Inflammatory Syndrome (IRIS) has been reported in patients treated with combination antiretroviral therapies. ***Adverse Reactions:*** (≥ 5%): diarrhea, dizziness, nausea, and rash
Key Points	Trogarzo is the first drug in a new class of antiretroviral medications that can provide significant benefit to patients who have run out of HIV treatment options. First HIV therapy with a new mechanism of action to be approved in the last 10 years.
Treatment Guidelines	HIV: Initial therapy generally consists of two nucleoside reverse transcriptase inhibitors (NRTI) combined with an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a PK-enhanced protease inhibitor (PI). Selection of the an initial regimen is based on various patient and regimen characteristics and specific clinical scenarios. Genotypic and resistance testing is recommended with treatment failure along with a new regimen.
Place in Therapy	Provide a treatment option for patients infected with difficult-to-treat multidrug resistant HIV.

ODACTRA®

(house dust mite allergen extract) tablet, for sublingual use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 3 – Non-preferred Brand
Formulary Alternatives	None.
FDA Approval	March 1, 2017
Therapeutic Class	Allergen-Specific Immunotherapy
Indications and Usage	Indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in adults 18 through 65 years of age.
Dosing	***Forms & Strengths:*** sublingual tablet ***Administration:*** take 1 tablet sublingually once daily ***Adjustments:*** None
Safety	***Contraindications:*** Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. A history of eosinophilic esophagitis. Hypersensitivity to any of the inactive ingredients contained in this product. ***Warnings:*** Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur. In case of oral inflammation or wounds, stop treatment with Odactra to allow complete healing of the oral cavity. ***Adverse Reactions:*** (≥ 5%): throat irritation/tickle, itching in the mouth, itching in the ear, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, nausea, tongue pain, throat swelling, tongue ulcer/sore on the tongue, stomach pain, mouth ulcer/sore in the mouth, and taste alteration/food tastes different.
Key Points	Odactra provides patients an alternative treatment to allergy shots to help address their symptoms.
Treatment Guidelines	Antihistamines, nasal corticosteroids, leukotriene receptor antagonists, cromolyn sodium, decongestants, subcutaneous immunotherapy, sublingual immunotherapy.
Place in Therapy	Provide an oral alternative to allergy shots for patients with house mite-induced allergic rhinitis.

SYMDEKO®

(tezacaftor/ivacaftor) tablet, (ivacaftor) tablet, for oral use

P&T Consideration	Drug is being removed from New to Market Block and can be added to the NCSHP 2017 Formulary.
Proposed Tier Placement	Tier 6 – Non-preferred Specialty
Formulary Alternatives	Orkambi (lumacaftor/ivacaftor), Kalydeco (ivacaftor)
FDA Approval	February 12, 2018
Therapeutic Class	Cystic fibrosis transmembrane conductance regulator (CFTR) modulator
Indications and Usage	Indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.
Dosing	***Forms & Strengths:*** co-packaged as tezacaftor 100 mg/ivacaftor 150 mg fixed dose combination tablets and ivacaftor 150 mg tablets. ***Administration:*** one tablet (containing tezacaftor 100 mg/ivacaftor 150 mg) in the morning and one tablet (containing ivacaftor 150 mg) in the evening, approximately 12 hours apart with a fat-containing food. ***Adjustments:*** Reduce dose in patients with moderate and severe hepatic impairment. Reduce dose when co-administered with drugs that are moderate or strong CYP3A inhibitors.
Safety	***Contraindications:*** None. ***Warnings:*** Elevated transaminases (ALT or AST), Use with CYP3A inducers, Cataracts ***Adverse Reactions:*** (≥ 3%): headache, nausea, sinus congestion, and dizziness
Key Points	SYMDEKO is an important treatment option for patients who either never started or discontinued ORKAMBI, and it also provides increased benefit over KALYDECO alone for patients with residual function mutations
Treatment Guidelines	Treatment of cystic fibrosis varies depending on severity of disease and age of patient. Ivacaftor is approved in patients age 2 and older, lumacaftor/ivacaftor is approved in patients age 6 and older, and tezacaftor/ivacaftor is approved in patients age 12 and older.
Place in Therapy	Provides a third treatment option (CFTR) for cystic fibrosis patients with specific CFTR gene mutations.

SPECIALTY GUIDELINE MANAGEMENT

SYMDEKO (tezacaftor/ivacaftor)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Symdeko is a combination of tezacaftor and ivacaftor, indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence.

If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: genetic testing report confirming the presence of the appropriate *CFTR* gene mutation.

III. CRITERIA FOR INITIAL APPROVAL

Cystic Fibrosis
Indefinite authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:

a. Genetic testing was conducted to detect a mutation in the *CFTR* gene.
b. The member has one of the following mutations in the *CFTR* gene: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, K1060T, L206W, P67L, R74W, R117C, R347H, R352Q, R1070W, S945L, S977F, 711+3A→G, 2789+5G→A, 3272-26A→G, 3849+10kbC→T, or the member is homozygous for the F508del mutation.
c. The member is at least 12 years of age.
d. Symdeko will not be used in combination with Kalydeco or Orkambi.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Utilization Management Policy Review

- New Policies Under Consideration
  - **DUPIXENT®** Enhanced Specialty Guideline Management
  - **ODACTRA®** Prior Authorization
  - **EUCRISA®** Prior Authorization, Step Therapy, Post Step Therapy
  - Topical Corticosteroids Prior Authorization with Quantity Limits

- Presented by:
  - Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

Dupixent Enhanced Specialty Guideline Management

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Dupixent is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: Member's chart or medical record to support inadequate treatment response to prerequisite topical therapies (refer to IV.2. below).

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a dermatologist or an allergist/immunologist.

IV. CRITERIA FOR INITIAL APPROVAL

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 18 years of age or older when all of the following criteria are met:
1. Affected body surface area is greater than or equal to 10%.
2. Member has had an inadequate treatment response to topical tacrolimus (Protopic) and at least two medium or higher potency topical corticosteroids in the past 180 days.

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response with Dupixent therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Odactra Prior Authorization Criteria

POLICY

FDA-APPROVED INDICATIONS

Odactra is an allergen extract indicated as immunotherapy for house dust mite (HDM) induced allergic rhinitis with or without conjunctivitis confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in persons 18 through 65 years of age.

Odactra is not indicated for the immediate relief of allergic symptoms

COVERAGE CRITERIA

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 house dust mite (HDM) induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for pollen-specific IgE antibodies for *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts.
  AND
- The patient does not have any of the following: severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy, history of eosinophilic esophagitis, medical conditions that may reduce the ability of the patient to survive a serious allergic reaction or increase the risk of adverse reactions after epinephrine administration and is not on any medication(s) that can inhibit or potentiate the effect of epinephrine
  AND
- The requested drug is being prescribed by or in consultation with an allergist/immunologist.

Eucrisa Step Therapy Criteria

POLICY

FDA-APPROVED INDICATIONS

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

INITIAL STEP THERAPY

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then a quantity limit will apply. If the patient is requesting more than the quantity limit, the claim will reject with a message indicating that a PA is required.

INITIAL LIMIT CRITERIA

Drug	1 Month Limit*	3 Month Limit*
Eucrisa (crisaborole)	60 grams (1 tube) per 25 days	180 grams (3 tubes) per 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.*

Eucrisa Prior Authorization Criteria

POLICY

FDA-APPROVED INDICATIONS

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

COVERAGE CRITERIA

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

- The requested drug is being prescribed for a patient 2 years of age or older for mild to moderate atopic dermatitis
  AND
  - The requested drug is being prescribed for use on sensitive skin areas (e.g., face, body skin folds, genital area, armpit, or around the eyes)
    AND
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor

  OR
  - The requested drug is being prescribed for use on non-sensitive (or remaining) skin areas
    AND
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid
- Coverage Duration for initial therapy is 3 months with a quantity limit not to exceed 60 gm per 30 days. Coverage for 120 gm per 30 days will be provided when 5% or greater body surface area is affected

OR

- The requested drug is being prescribed for continuation of therapy, and the patient achieved or maintained positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation of papules), lichenification (epidermal thickening), OR pruritus (itching)].
- Coverage Duration for continuation of therapy is 12 months with a quantity limit not to exceed 60 gm per 30 days. Coverage for 120 gm per 30 days will be provided when 5% or greater body surface area is affected

Topical Corticosteroids Prior Authorization Criteria

COVERAGE CRITERIA

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

- The requested drug is being prescribed for a corticosteroid-responsive dermatoses or condition (e.g., eczema, atopic dermatitis, seborrheic dermatitis, psoriasis)

AND

- The patient has experienced an inadequate treatment response to at least a 14 day trial of one generic topical corticosteroid (e.g., alclometasone, clobetasol, desoximetasone, fluocinolone, mometasone, etc.)

  OR
- The patient was unable to complete a 14 day trial of generic topical corticosteroids due to an intolerable adverse reaction that is documented in the patient's chart

Quantity Limits may apply.

INITIAL QUANTITY LIMIT

The initial quantity limit for all topical corticosteroids included in this limit/post limit criteria is set to 120 units per month. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

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

- Coverage for a greater quantity is provided when an additional quantity is necessary to adequately treat the patient's condition.

Quantity limits apply.

Topical Corticosteroids Max Quantity Limits

Current plan approved criteria cover up to:

- 430 grams of Trianex
- 240 grams Aclovate
- 240 grams or milliliters of Cordran cream/lotion
- 240 milliliters of Cutivate lotion
- 240 grams of Desonate
- 240 grams of DesOwen cream
- 240 milliliters of Nolix
- 240 grams of Synalar
- 240 grams of Tridesilon
- 180 grams of Apexicon E
- 180 milliliters of Clobex Lotion
- 180 grams of Cordran ointment
- 180 grams of Dermatop
- 180 milliliters of DesOwen lotion
- 180 milliliters of Diprolene lotion
- 180 milliliters of Elocon lotion
- 180 grams or milliliters of Locoid
- 180 grams of Locoid Lipocream
- 180 milliliters of LoKara,
- 180 grams of Psorcon
- 180 grams of Temovate gel
- 180 grams of Temovate E
- 180 grams of Topicort
- 180 milliliters of Ultravate lotion
- 180 grams of Westcort
- 160 grams of Pandel
- 150 grams of Cloderm
- 150 grams of Cutivate cream
- 150 grams of Diprolene ointment
- 150 grams of Diprolene AF
- 150 grams of Elocon cream/ointment
- 150 grams of Halog
- 150 grams of Impoyz cream
- 150 grams of Temovate cream/ointment
- 150 grams of Ultravate cream/ointment
- 150 grams of Vanos

Utilization Management Policy Review

- Existing Policies Currently in Effect
  - **PRALUENT®** Specialty Guideline Management
  - **REPATHA®** Specialty Guideline Management
  - Omega-3 Prior Authorization
  - **PROLIA®** Specialty Guideline Management
  - **XGEVA®** Specialty Guideline Management

- Presented by:
  - Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

Praluent & Repatha Specialty Guideline Management

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Members with established atherosclerotic cardiovascular disease.
B. Members with an untreated LDL-C of greater than, or equal to, 190 mg/dL

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Clinical atherosclerotic cardiovascular disease (ASCVD)
Authorization of 12 months may be granted when all of the following criteria are met:
1. The member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event
2. The member has a current LDL-C level greater than, or equal to, 70 mg/dL
3. The member is receiving maximally tolerated statin therapy or is statin intolerant

B. Primary or familial hyperlipidemia
Authorization of 12 months may be granted when all of the following criteria are met:
1. The member had an untreated (before any lipid lowering therapy) LDL-C level greater than, or equal to, 190 mg/dL
2. The member has a current LDL-C level greater than, or equal to, 100 mg/dL
3. The member is receiving maximally tolerated statin therapy or is statin intolerant

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who are continuing therapy with a PCSK9i.

Omega-3 Fatty Acids Prior Authorization Criteria

COVERAGE CRITERIA

Omega-3 Fatty Acids will be covered with prior authorization when the following criteria are met:

- The patient has, or did have prior to the start of a triglyceride lowering drug, a triglyceride level greater than or equal to 500 mg/dL
  AND
- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment

Prolia Specialty Guideline Management

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Treatment to increase bone mass in men with osteoporosis at high risk for fracture
3. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer
4. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

B. Compendial Uses
Prevention or treatment of osteoporosis during androgen deprivation therapy for patients with high fracture risk

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Osteoporosis in Postmenopausal Women
Authorization of 24 months may be granted to postmenopausal female members when ANY of the following criteria are met:
1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score of ≤ -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
   a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk)
   b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo])
   c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

B. Osteoporosis in Men
Authorization of 24 months may be granted to male members with osteoporosis when ANY of the following criteria are met:
1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member has a pre-treatment T-score of ≤ -2.5
3. Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

C. Breast Cancer
Authorization of 24 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer.

D. Prostate Cancer
Authorization of 24 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Xgeva Specialty Guideline Management

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Prevention of skeletal-related events in patients with bone metastases from solid tumors
   Limitation of Use: Not indicated for the prevention of skeletal-related events in patients with multiple myeloma
2. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
3. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Bone Metastases from a Solid Tumor (excluding prostate cancer)
Authorization of 24 months may be granted for the prevention of skeletal-related events in members with bone metastases from solid tumors other than prostate cancer.

B. Prostate Cancer
Authorization of 24 months may be granted for the prevention of skeletal-related events in members with bone metastases for castration recurrent prostate cancer.

C. Giant Cell Tumor of Bone
Authorization of 24 months may be granted for the treatment of giant cell tumor of bone.

D. Hypercalcemia of Malignancy
Initial authorization of 2 months may be granted for the treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy (e.g., zoledronic acid, pamidronate) OR there is a clinical reason to avoid IV bisphosphonate therapy (See Appendix A).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Next meeting: August 21, 2018

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

www.shpnc.org

www.nctreasurer.com