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 5/1/18

Pharmacy & Therapeutics Committee Meeting

February 20, 2018
6:30 – 8:00 PM

WELCOME

New Committee Members:

- Peter Robie, MD
  - General Internist practicing in Winston-Salem
  - SHP Board of Trustees member

- Tony Gurley, RPh
  - Entrepreneur, pharmacist and lawyer
  - Pharmacy Manager at Glenwood South Pharmacy

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 starting on page four of the P&T Booklet.
- Are there any additions or corrections to the minutes?
  - If not, the minutes will stand approved as is.

Old Business – P&T Bylaws

Purpose of Bylaws:

- Pursuant to N.C.G.S. §§ 135-48.51(2) and 58-3-221(a)(1)
- Set up basic rules, operating standards, and procedures the Committee will follow

Overview of Bylaws:

- To maintain consistency and mirrors the BOT Bylaws
- Bylaws defines the following areas:
  - Membership
  - Appointments
  - Terms
  - Meetings
  - Operations
  - Role

Old Business – Summary 2018 Formulary Strategy

- Accepted CVS Standard Formulary with the following exceptions:
  - JARDIANCE®, SYNJARDY® & SYNJARDY® XR will remain preferred products, while INVOKANA®, INVOKAMET® & INVOKAMET® XR will not be covered
  - HORIZANT® will remain covered as a preferred product
- Will adopt the CVS Enhanced MME-based Opioid Management on 3/1/2018
- Removed the following Prior Authorizations:
  - Buprenorphine & buprenorphine/naloxone
  - DIFICID®
- Terminated our custom Exceptions process and replaced with CVS Standard
- Enacted the Specialty Quantity Limit Program
- Adopted the following new Prior Authorizations/Quantity Limit/Step Therapy criteria:
  - Long-acting Insulin / GLP-1 Agonist
  - HMG-COA Reductase Inhibitor (statin)

Formulary Updates – Effective 5/1/2018

- CVS Caremark's Quarterly Formulary Update
  - Drug Removals
  - 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
  - ALEVICYN® (desonide, hydrocortisone) all formulations
    - Preferred options are generic desonide and hydrocortisone

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- Advanced Controlled Specialty Formulary Removals
  - Remove brand name medications with readily available, clinically appropriate and more cost-effective formulary alternatives
  - BUPHENYL® (sodium phenylbutyrate) powder and tablets
  - RAVICTI® (glycerol phenylbutyrate) liquid
    - The preferred option is sodium phenylbutyrate

Formulary Updates – Specialty Product Movement

- CVS determined that a small number of therapy classes may no longer fit the specialty drug list definition (such as a combination of high cost, complex therapy, adherence challenges, and limited distribution/narrow networks)
- The following classes would be removed from the specialty drug list:
  - Allergen Immunotherapy:
    - ORALAIR®
  - Botulinum Toxins Category and associated drugs:
    - BOTOX®, DYSPORT®, MYOBLOC®, XEOMIN®
  - Osteoarthritis and associated drugs:
    - MONOVISC®, GENVISC® 850, HYMOVIS®, EUFLEXXA®, GEL ONE®, GELSYN-3®, HYALGAN®, ORTHOVISC®, SUPARTZ®, SYNVISC®, SYNVISC ONE®
  - Contraceptives:
    - IMPLANON®, KYLEENA®, LILETTA®, MIRENA®, NEXPLANON®, SKYLA®
- The listed medications will be available at a lower tier on the regular drug formulary, however; products that are excluded from the formulary will continue to reject as such.

Formulary Updates – Specialty Product Movement

- One product was added to CVS Health's specialty drug list

- XYREM®
  - Controlled substance indicated for the treatment of narcolepsy
  - REMS program
  - Inventory controlled via limited distribution
  - Utilization Management program
  - Currently is on the formulary at tier 3

- The product will be moved to the Specialty Drug List and uptiered to 6
  - Utilization Management program will remain in effect

Formulary Updates – Uptiers

- Typically branded medications that have:
  - Readily available generic alternatives or,
  - Other preferred formulary alternatives in the therapeutic class

- BRISDELLE® (paroxetine mesylate) capsules
  - *Preferred option is generic paroxetine mesylate*
- JUXTAPID® (lomitapide) capsules
  - *Preferred option is REPATHA® (evolocumab) or PRALUENT® (alirocumab)*
- RENVELA® (sevelamer) packets and tablets
  - *Preferred options include generic calcium acetate, lanthanum carbonate, sevelamer carbonate, PHOSLYRA® (calcium acetate), and VELPHORO® (sucroferric oxyhydroxide)*
- TAMIFLU® (oseltamivir) capsules and suspension
  - *Preferred options include generic oseltamivir and RELENZA® (zanamivir)*

Formulary Updates – Downtiers

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

- **AUSTEDO®** (deutetrabenazine) tablets
- **KYLEENA®** (levonorgestrel-releasing intrauterine system) IUD
- **MIRENA®** (levonorgestrel-releasing intrauterine system) IUD
- **SKYLA®** (levonorgestrel-releasing intrauterine system) IUD
- **ODOMZO®** (sonidegib) capsules
- **CYSTAGON®** (cysteamine bitartrate) capsules
- ESTRING® (estradiol vaginal ring)
- OMNIPOD® (continuous subcutaneous insulin infusion pump)
- TOLAK® (fluorouracil) cream

BOLDED medications indicate specialty drug designation

Formulary Updates – New Drug Additions

- New-to-Market Block
  - 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 placed on CVS's New-to-Market Block
  - These medications are reviewed by the members of the Plan's P&T Committee

Formulary Updates – New Drug Additions

- New formulations or strengths of drugs already on the formulary

DRUG NAME	DRUG NAME
Varubri (rolapitant)	Trelegy Ellipta (fluticasone/umeclidinium/vilanterol)
Qtern (dapagliflozin/saxagliptin)	Opdivo (nivolumab)
Tracleer (bosentan)	Prolastin-C (alpha-1 proteinase)
Zenpep (pancrelipase)	Xigduo XR (dapagliflozin/metformin)
Retin-A Micro Gel (tretinoin)	Actimmune (interferon gamma-1b)
Odomzo (sonidegib)	Jadenu (deferasirox)
Trisenox (arsenic trioxide)	Adzenys ER (amphetamine ER)
Stelara (ustekinumab)	Fiasp (insulin aspart)
Tolak (fluorouracil)	Romidepsin
Fibryga (fibrinogen)	Methylphenidate ER / gemcitabine

Formulary Updates – New Drug Additions

- New molecular entities being added to the formulary

DRUG NAME
Calquence (acalabrutinib)
Fasenra (benralizumab)
Hemlibra (emicizumab-kxwh)
Verzenio (abemaciclib)

CALQUENCE® (acalabrutinib)

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.

CALQUENCE® (acalabrutinib)

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.

IV. REFERENCES

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2017.

VERZENIO® (abemaciclib)

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

VERZENIO® (abemaciclib)

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.

IV. REFERENCES

1. Verzenio [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2017.
2. Dickler MN, Tolaney SM, Rugo HS, et al. MONARCH 1, a phase II study of abemaciclib, a CDK4 and CDK6 inhibitor, as a single agent, in patients with refractory HR+/HER2- metastatic breast cancer. *Clin Cancer Res*. 2017;23(17):5218-5224.
3. Sledge, GW Jr, Toi M, Neven P, et al. MONARCH 2: abemaciclib in combination with fulvestrant in women with HR+/HER2- advanced breast cancer who had progressed while receiving endocrine therapy. *J Clin Oncol*. 2017;35(25):2875-2884.

FASENRA® (benralizumab)

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	Nucala (mepolizumab)
FDA Approval	November 14, 2017
Therapeutic Class	Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa)
Indications and Usage	Indicted for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype
Dosing	***Forms & Strengths:*** 30 mg.ml solution in a single-dose prefilled syringe ***Administration:*** 30 mg subcutaneously every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter ***Adjustments:*** (≥5%) include headache and pharyngitis
Safety	***Contraindications:*** Known hypersensitivity to benralizumab or excipients ***Warnings:*** Hypersensitivity reactions, treat parasitic (helminth) infections before starting therapy, gradual reduction in corticosteroid dosage ***Adverse Reactions:*** (≥ 3%) headache, pyrexia, pharyngitis, and hypersensitivity reactions
Key Points	First respiratory biologic with an 8-week maintenance dosing schedule. Up to 51% reduction in the annual exacerbation rate (AAER) versus placebo, significant improvement in lung function and a 75% reduction in daily oral steroid use.
Treatment Guidelines	The 2017 Global Strategy for Asthma Management and Prevention guideline by GINA currently recommends referral to a specialist for consideration of add-on treatment in patients with persistent symptoms and exacerbations despite adherence with medium or high dosage ICS and LABA and in whom other controller options (e.g. Spiriva Respimat, theophylline) have been considered. Add-on treatment options include anti-IgE (Xolair [omalizumab]), and anti-IL-5 (Nucala and Cinqair) agents depending on asthma phenotype. Other options include low dose oral corticosteroids and Spiriva Respimat (if not previously used).
Place in Therapy	Fasenra is the third FDA-approved drug after Nucala and Cinqair (reslizumab) for severe asthma as add-on therapy in patients with an eosinophilic phenotype and provides another treatment option for these patients.

FASENRA® (benralizumab)

SPECIALTY GUIDELINE MANAGEMENT

FASENRA (benralizumab)

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
Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitations of Use:
- Not for treatment of other eosinophilic conditions
- Not for relief of acute bronchospasm or status asthmaticus

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

II. CRITERIA FOR INITIAL APPROVAL

Severe eosinophilic asthma
Authorization of 12 months may be granted for treatment of severe asthma with an eosinophilic phenotype when all of the following criteria are/is met:
A. Member is 12 years of age or older
B. Member has a baseline blood eosinophil count of at least 300 cells per microliter
C. Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses:
   1. Inhaled corticosteroid
   2. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for treatment of severe asthma with an eosinophilic phenotype when ALL of the following criteria are met:
A. Member is 12 years of age or older
B. Asthma control has improved on Fasenra treatment, demonstrated by either:
   1. A reduction in the frequency and/or severity of symptoms and exacerbations
   2. A reduction in the daily maintenance oral corticosteroid dose

IV. REFERENCES

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca; November 2017.
2. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med. 2017;376:2448-2458*

HEMLIBRA® (emicizumab-kxwh)

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	Orphan Drug – First in Class Status
FDA Approval	November 16, 2017, Priority Review; Breakthrough therapy and Orphan drug designations
Therapeutic Class	Factor VIII mimetic/Monoclonal antibody (MAB)
Indications and Usage	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.
Dosing	***Forms & Strengths:*** 30 mg/mL; 60 mg/0.4mL; 105 mg/0.7mL; 150 mg/mL ***Administration:*** 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly. ***Adjustments:*** None
Safety	***Contraindications:*** None ***Warnings:*** Boxed warning for thrombotic microangiopathy and thromboembolism. Cases of thrombotic microangiopathy and thrombotic events were reported when on average a cumulative amount of >100 U/kg/24 hours of activated prothrombin complex concentrate was administered for 24 hours or more to patients receiving HEMLIBRA prophylaxis. Monitor for the development of thrombotic microangiopathy and thrombotic events if aPCC is administered. Discontinue aPCC and suspend dosing of HEMLIBRA if symptoms occur. ***Adverse Reactions:*** (≥10%) are injection site reaction, headache and arthralgia.
Key Points	Emicizumab is a recombinant monoclonal antibody that substitutes the function of blood coagulation factor VIII. Emicizumab simultaneously binds factor IXa and factor X, exerting the same function as factor VIII and is not expected to be susceptible to neutralizing antibodies that may develop against intravenous factor VIII replacement therapies.
Treatment Guidelines	A first in class treatment to prevent bleeding episodes in patients with hemophilia A who have developed antibodies (Factor VIII inhibitors).
Place in Therapy	Once-weekly dosing of emicizumab has high bioavailability when given subcutaneously and is expected to improve patient usability.

HEMLIBRA® (emicizumab-kxwh)

SPECIALTY GUIDELINE MANAGEMENT

HEMLIBRA (emicizumab-kxwh)

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. FDA-Approved Indications
Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors

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

II. REQUIRED INFORMATION

High-inhibitor titer (i.e., ≥ 5 Bethesda units per milliliter [BU/mL]) as confirmed by laboratory testing

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of hemophilia A (congenital factor VIII deficiency) with inhibitors when member has a history of high-inhibitor titer (i.e., ≥ 5 Bethesda units per milliliter [BU/mL]) as confirmed by laboratory testing.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve and maintain reduction in the frequency of bleeding episodes.

V. REFERENCES

1. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.
2. Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med. 2017; 377:809-818.
3. A Study of Emicizumab Administered Subcutaneously (SC) in Pediatric Participants With Hemophilia A and Factor VIII (FVIII) Inhibitors (HAVEN 2). ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). June 10, 2016. Identifier: NCT02795767. Available at https://clinicaltrials.gov/ct2/show/NCT02795767. Accessed November 20, 2017.
4. Srivastava A, Brewer A, Street A, et al. Guidelines for the management of hemophilia. Haemophilia. January 2013;19(1):e1-e47. Available at https://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed November 20, 2017.
5. Kruse-Jarres R, Kempton CL, Baudo F, et al. Acquired hemophilia A: Updated review of evidence and treatment guidance. Am J Hematol. 2017;92:695–705.

Utilization Management Policy Review

- New Policies Under Consideration
  - Proton Pump Inhibitors Quantity Limit; Post Limit Prior Authorization
  - ZEGERID® Initial Prior Authorization
  - ULORIC® Initial Step Therapy; Post Step Therapy Prior Authorization
  - ACTICLATE® Initial Step Therapy; Post Step Therapy Prior Authorization

- Existing Policies Currently in Effect
  - 5-HT1 Agonist Quantity Limit; Post Limit Prior Authorization
  - MIGRANAL Quantity Limit
  - Butorphanol Quantity Limit; Post Limit Prior Authorization
  - Lidocaine Quantity Limit; Post Limit Prior Authorization

Utilization Management Policy Review

- Proton Pump Inhibitors Quantity Limit
  - The limit for the whole proton pump inhibitor (PPI) class is a total of a 90 units of therapy per 365 days, regardless of the strength.
  - If the patient requires more than 90 units of therapy per 365 days, please refer to the Post Limit PA criteria for the PPIs.

- Proton Pump Inhibitors Post Limit Prior Authorization
  - Proton Pump Inhibitors will be covered with prior authorization when the following criteria are met:
    - The requested drug is being prescribed for any of the following:
      - A) Endoscopically verified peptic ulcer disease
      - B) Frequent and severe symptoms of chronic gastroesophageal reflux disease (GERD)
      - C) Atypical symptoms or complications of GERD

      OR
      - The patient is at high risk for GI adverse events. [Note: Risk factors for serious GI adverse events include, but are not limited to, the following: chronic NSAID therapy, history of peptic ulcer disease and/or GI bleeding, treatment with oral corticosteroids, treatment with anticoagulants, poor general health status, or advanced age.]

      OR
      - The requested drug is being prescribed for any of the following:
        - A) Barrett's esophagus as confirmed by biopsy,
        - B) Hypersecretory syndrome, such as Zollinger-Ellison, confirmed with a diagnostic test

Utilization Management Policy Review

- ZEGERID® Initial Prior Authorization

COVERAGE CRITERIA

Zegerid (omeprazole/sodium bicarbonate) will be covered with prior authorization when the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance or contraindication to THREE generic proton pump inhibitors

AND

- The requested drug is being prescribed for treatment of gastroesophageal reflux disease (GERD) OR duodenal ulcer OR gastric ulcer

  OR
- The requested drug is being prescribed for the maintenance of healing of erosive esophagitis

Utilization Management Policy Review

- ULORIC® Initial Step Therapy
  - Filled a prescription for a 30 day supply of allopurinol within the last 180 days, the claim will pay

- ULORIC® Post Step Therapy Prior Authorization

COVERAGE CRITERIA

Uloric (febuxostat) will be covered with prior authorization when the following criteria are met:

- Patient has experienced an intolerance or inadequate treatment response to allopurinol

OR

- The requested drug is being prescribed for gout AND the patient has a contraindication to allopurinol

Utilization Management Policy Review

- ACTICLATE® Initial Step Therapy
  - Filled a prescription for a 7 day supply of generic doxycycline within the past 60 days, the claim will pay

- ACTICLATE® Post Step Therapy Prior Authorization

COVERAGE CRITERIA

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

- Patient has experienced an inadequate treatment response to generic doxycycline

Utilization Management Policy Review

- 5-HT1 Agonist Quantity Limit
  - Differs depending on the medication

- 5-HT1 Agonist Post Limit Prior Authorization
  - Quantity Limits apply per the Limit Criteria chart on policy

COVERAGE CRITERIA

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

- The patient does not have confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension
- The plan provides coverage up to an amount sufficient for treating eight headaches per month at the maximum daily dose of the prescribed drug. The patient does not need an amount for treating more than eight headaches per month with a 5-HT1 agonist

AND

- The patient has a diagnosis of migraine headache
  - The patient is currently using migraine prophylactic therapy or unable to take migraine prophylactic therapies due to inadequate response, intolerance or contraindication
    [Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]
  - Medication overuse headache has been considered and ruled out

OR.

- The request is for sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray (Imitrex Inj, Imitrex NS, Sumavel DosePro, Zomig NS) for the treatment of cluster headache

Utilization Management Policy Review

- MIGRANAL Quantity Limit

LIMIT CRITERIA		
Drug	**1 Month Limit***	**3 Month Limit***
Migranal	8 nasal units (1 kit)/25 days	24 nasal units (3 kits)/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.*

Utilization Management Policy Review

- Butorphanol Quantity Limit

LIMIT CRITERIA		
Drug	**1 Month Limit***	**3 Month Limit***
butorphanol nasal spray	2 bottles / 25 days	6 bottles / 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.*

- Butorphanol Post Limit Prior Authorization

COVERAGE CRITERIA

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

- The patient has a diagnosis of migraine headache.
- Medication overuse headache has been ruled out.
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to abortive migraine therapy.
- The patient is currently using migraine prophylactic therapy or has experienced an inadequate treatment response, intolerance, or contraindication to migraine prophylactic therapy

AND

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least 2 oral opioids
  OR
- The patient is unable to take oral medications, including liquids

Quantity Limits apply.

4 bottles / 25 days
12 bottles / 75 days

Utilization Management Policy Review

- Lidocaine Quantity Limit

LIMIT CRITERIA

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.

Drug	1 Month Limit and 3 Months Limit*
Emla 2.5%-2.5% cream lidocaine -prilocaine 2.5-2.5% cream	30 gm / 25 days
Lidocaine 2% gel	30 gm / 25 days
Lidocaine 4% gel	30 gm / 25 days
Lidocaine 5% ointment	50 gm / 25 days
Lidocaine 4% solution	50 mL / 25 days
Pliaglis 7-7% cream Lidocaine-tetracaine 7-7% cream	30 gm / 25 days
Synera 70-70mg patch Lidocaine-tetracaine 70-70mg patch	2 patches / 25 days

** The duration of 25 days is used for a 30-day fill period to allow time for refill processing.*

**** These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit.***

Utilization Management Policy Review

- Lidocaine Post Limit Prior Authorization

COVERAGE CRITERIA

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

- Lidocaine 5% ointment is being prescribed for any of the following:
  - Production of anesthesia of accessible mucous membranes of the oropharynx
  - As an anesthetic lubricant for intubation
  - For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites

  OR
- Lidocaine-prilocaine 2.5-2.5% cream (Emla) is being prescribed as a topical anesthetic for use on either
  - Normal intact skin for local analgesia
  - Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia

  OR
- Lidocaine hcl 2% gel is being prescribed for any of the following:
  - Prevention and control of pain in procedures involving the urethra
  - Topical treatment of painful urethritis
  - As an anesthetic lubricant for endotracheal intubation (oral and nasal)

  OR
- Lidocaine hcl 4% gel is being prescribed for any of the following:
  - Stage I - IV pressure ulcers
  - Venous stasis ulcers
  - Ulcerations caused by mixed vascular etiologies
  - Diabetic skin ulcers
  - First and second degree burns
  - Post-surgical incisions, cuts and abrasions

  OR
- Lidocaine hcl 4% topical solution is being prescribed for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract

  OR
- Lidocaine-tetracaine 7-7% cream (Pliaglis) is being prescribed for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal

  OR
- Lidocaine-tetracaine 70-70mg patch (Synera) is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions

AND

The requested drug will not be used as part of a compounded product.

Quantity Limits apply.

Utilization Management Policy Review

- Lidocaine Post Limit Prior Authorization

***POST LIMIT QUANTITY**

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.

Drug	Quantities to approve per 25 days*
EMLA 2.5%-2.5% cream lidocaine -prilocaine 2.5-2.5% cream	60 gm
Lidocaine 2% gel	60 gm
Lidocaine 4% gel	60 gm
Lidocaine 5% ointment	100 gm
Lidocaine 4% solution	100 mL
Pliaglis 7-7% cream Lidocaine-tetracaine 7-7% cream	60 gm
Synera 70-70mg patch Lidocaine-tetracaine 70-70mg patch	4 patches

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Next meeting: MAY 22, 2018

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

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