WRITTEN SECTION REPORTS

(REPORT PERIOD JUNE SEPTEMBER 23, 2017 THROUGH DECEMBER 8, 2017)

1. Policies Presented to the N.C. Physician Advisory Group (PAG)

The N.C. Physician Advisory Group met on 09/28/17, 10/26/17 and 12/07/17
The Pharmacy & Therapeutic Committee met on 10/10/17 and 11/14/17

Recommended Policies

- 1A-4, Cochlear and Auditory Brainstem Implants – 09/28/17
- 2B-1, Nursing Facility Services – 09/28/17
- 11B-4, Kidney (Renal) Transplant – 09/28/17
- 3B, Program of All-Inclusive Care for the Elderly (PACE) – 10/26/17
- 3A, Home Health Services - 12/7/17
- 5A-2, Respiratory Equipment & Supplies – 12/7/17

Recommended Pharmacy

- PA Criteria Nuplazid – 09/28/17
- PA Criteria Hepatitis C Virus Medications (Mavyret & Vosevi) – 09/28/17
- PA Criteria Opioid Dependence Therapy Agents – 10/26/17
- PA Criteria Systemic Immunomodulators – 10/26/17
- PA Criteria Treatment for Movement Disorders (Ingrezza)– 10/26/17
- PA Criteria Neuromuscular Blocking Agents (Dysport) – 12/7/17
- PA Criteria Systemic Immunomodulators (Renflexis)- 12/7/17
- PDL: Biguanides and Combinations: Glumetza – 12/7/17

PAG Notification

- 5A-1, Physical Rehabilitation Equipment and Supplies – 10/27/17
- 5A-2, Respiratory Equipment and Supplies – 10/27/17
- 5A-3, Nursing Equipment and Supplies – 10/27/17

2. Policies posted for Public Comment

- PA Criteria Hepatitis C Virus Medications – 09/13/17
- Preferred Drug List (Renvela)– 09/13/17
- 11B-4, Kidney (Renal) Transplant – 10/11/17
- 2B-1, Nursing Facility Services – 10/13/17
- PA Criteria Nuplazid – 10/25/17
- 1A-4, Cochlear and Auditory Brainstem Implants – 10/25/17
- PA Criteria Opioid Dependence Therapy Agents – 10/27/17
- 5A-1, Physical Rehabilitation Equipment and Supplies – 10/27/17
- 5A-2, Respiratory Equipment and Supplies – 10/27/17
- 5A-3, Nursing Equipment and Supplies – 10/27/17
- 3B, Program of All-Inclusive Care for the Elderly (PACE) – 11/01/17
- PA Criteria Treatment for Movement Disorders (Ingrezza) – 11/01/17
- PA Criteria Systemic Immunomodulators (Kevzara & Orencia) – 11/01/17
- PA Criteria Opioid Analgesics (STOP Act) – 11/28/17

3. New or Amended policies posted to Medicaid website

- 1A-28, Visual Evoked Potential (VEP) – 10/01/17
- 1E-1, Hysterectomy – 10/01/17
- 1E-2, Therapeutic and Non-therapeutic Abortions – 10/01/17
- 1E-3, Sterilization Procedures – 10/01/17
- 9A, Over-The-Counter Products – 10/01/17
- 10A, Outpatient Specialized Therapies – 10/15/17
- 1A-13, Ocular Photodynamic Therapy – 11/01/17
- 1B-1, Botulinum Toxin Treatment: Type A (Botox) and Type B (Myobloc) – 11/01/17
- 1B-3, Intravenous Iron Therapy – 11/01/17
- 1S-8, Drug Testing for Opioid Treatment and Controlled Substance Monitoring – 11/01/17
- 1T-2, Special Ophthalmological Services – 11/01/17
- 3G-1, Private Duty Nursing for Beneficiaries Age 21 and Older – 11/01/17
- 3G-2, Private Duty Nursing for Beneficiaries Under 21 Years of Age – 11/01/17
- 1G-2, Skin Substitutes – 11/14/17
- 1-I, Dietary Evaluation and Counseling and Medical Lactation Services – 12/01/17

4. Outpatient Pharmacy

Opioid Dependence Therapy Agents Coverage Changes

Effective Nov. 1, 2017, **Suboxone Film** (the preferred product in this class) will no longer require a prior approval for coverage. The beneficiary must be receiving the medication for a diagnosis of Opioid Dependence and the prescriber must have a special DEA number that begins with "X". The maximum covered daily dose is 24 mg/day.

For coverage of **Bunavail Film** (non-preferred), the beneficiary must be receiving the medication for a diagnosis of opioid dependence and the prescriber must have a special DEA number that begins with "X". The beneficiary must have tried and failed on Suboxone Film or have a documented medical reason why they cannot use Suboxone Film. The maximum covered daily dose is 12.6mg/day.

For coverage of **buprenorphine-naloxone sublingual tablets** (non-preferred), the beneficiary must be receiving the medication for a diagnosis of opioid dependence and the prescriber must have a special DEA number that begins with "X". The beneficiary must have tried and failed on Suboxone Film or have a documented medical reason why they cannot use Suboxone Film. The maximum covered daily dose is 24mg/day.

For coverage of **Zubsolv** (non-preferred), the beneficiary must be receiving the medication for a diagnosis of opioid dependence and the prescriber must have a special DEA number that begins with "X". The beneficiary must have tried and failed on Suboxone Film or have a documented medical reason why they cannot use Suboxone Film. The maximum covered daily dose is 17.1mg/day.

A prior approval is required for coverage of **buprenorphine sublingual tablets** (single ingredient), which are also non-preferred. The prescriber must have a special DEA number that begins with "X" and the beneficiary must be unable to take Suboxone Film. Acceptable reasons include: beneficiaries who are pregnant or nursing, (documentation should be provided with the prior approval request) and beneficiaries with an allergy to naloxone (documentation should be provided with the prior approval request), which includes the following signs and symptoms: rashes, hives, pruritus, bronchospasm, angioneurotic edema and/or anaphylactic shock. Initial requests and renewal requests require documentation as to why the beneficiary cannot use a combination product.

Requests for **buprenorphine** (single ingredient) may be approved for up to nine months during pregnancy and in two month increments thereafter during breast feeding. The maximum daily dose covered is 24 mg/day. Initial requests and renewals require documentation as to why the beneficiary cannot use a combination (buprenorphine-naloxone) product. Requests for buprenorphine (single ingredient) product may be approved for up to 12 months for beneficiaries with a

documented allergy to naloxone. The maximum daily dose covered is 24 mg/day. Initial requests and renewal requests require documentation as to why the beneficiary cannot use a combination (buprenorphine-naloxone) product.

NC Medicaid and N.C. Health Choice Preferred Drug List (PDL) Changes

Effective **Nov. 1, 2017**, the N.C. Division of Medical Assistance (DMA) will implement approved changes to the N.C. Medicaid and N.C. Health Choice Preferred Drug List (PDL).

Below are a few highlights of the changes:

Opioid Analgesics

- This class name was updated from "Narcotic Analgesics" to "Opioid Analgesics"
- Opana ER will be removed from the PDL as it has been discontinued from the market

Anti-Infective-Systemic (Antibiotics - Inhaled)

- A new PDL drug class has been added. It is "Anti-Infective-Systemic (Antibiotics- Inhaled)." This class requires a trial and failure of only one preferred drug

Antiviral (Hepatitis C Agents)

- Mayvret (for 8 weeks of therapy) will be preferred for all genotypes without cirrhosis
- Mayvret (for 12 weeks of therapy) will be preferred for all genotypes with compensated cirrhosis (Child Pugh A)
- Epclusa Tablet (in combination with ribavirin) will be preferred for all genotypes with decompensated cirrhosis (Child Pugh B and C)
- Vosevi will be preferred for all genotypes previously treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor
- Harvoni Tablet will remain preferred until April 30, 2018, only for beneficiaries who start Harvoni therapy prior to Nov. 1, 2017, to allow for completion of the therapy

Behavioral Health (Antihyperkinesis/ADHD)

- Metadate CD capsules have been removed from the PDL as they are discontinued
- Clonidine ER tablet (generic for Kapvay), Desoxyn Tablet (methamphetamine HCl), dextroamphetamine ER capsule (generic for Dexedrine Spansules), all methylphenidate ER tablets, Ritalin LA Capsule (methylphenidate 20 mg, 30 mg, 40 mg, 60 mg) will move from preferred to non-preferred
- Quillichew ER Oral (methylphenidate), Vyvanse Chewable Tablets and Aptensio XR will move from non-preferred to preferred

Cardiovascular (ACE Inhibitors)

- Qbrelis Solution (Lisinopril) will be non-preferred, with an age exemption allowed for children less than 12 years of age

Endocrinology (Growth Hormone)

- Nutropin AQ Pen / Nuspin (somatropin) will move from preferred to non-preferred status
- Genotropin Cartridge / Miniquick (somatropin) will move from non-preferred to preferred status

Endocrinology (Hypoglycemics – Injectable)

- Humalog Kwikpen will move from preferred to non-preferred status (Rapid Acting Insulin)
- Humulin R-U500 Kwikpen will be added as a new non-preferred drug (Short Acting Insulin)
- Humulin N Pen will move from preferred to non-preferred status (Intermediate Acting Insulin)
- Basaglar Kwikpen (insulin glargine) will be added as a new non-preferred drug (Long Acting Insulin)
- Humulin 70/30 Pen will move from preferred to non-preferred status (Combination Insulin)

Endocrinology (Hypoglycemics – Oral- Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor and Combinations)

- Farxiga Tablet (dapagliflozin) and Jardiance Tablet (empagliflozin) will move from non-preferred to preferred status.
- Invokana and Invokamet will move from preferred to non-preferred status
- Added Synjardy XR and Invokamet XR tablet as a new non-preferred product

Respiratory (COPD Agents)

- Combivent Respimat Inhalation Spray will move from preferred to non-preferred status.
- Stiolto Respimat Inhalation Spray will move from non-preferred to preferred status

Topicals (Immunomodulators- Atopic Dermatitis)

- Eucrisa 2% Ointment will move from non-preferred to preferred status. Clinical criteria continues to apply.

Topicals (Steroids, Low Potency)

- Desonide cream/ointment (generic for DesOwen) will move from preferred to non-preferred status with an age exemption allowed for children less than 12 years of age.

These changes could affect pharmacy stocking needs, generic substitution, product substitution, and Point of Sale (POS) overrides. If a brand is Preferred with a Non-Preferred generic equivalent, "brand medically necessary" is NOT needed on the face of the prescription. Below is a chart of preferred brands with non-preferred generics.

As a reminder, a 72-hour emergency supply may be provided if a prescription is awaiting prior authorization. A "3" in the Level of Service field (418-DI) should be used to indicate that the transaction is an emergency fill.

2017-2018 NC Medicaid and Health Choice Preferred Drug List
Preferred Brands with Non-Preferred Generic Alternatives
Effective 11-1-2017 ***(bold items are newly preferred)***

Preferred Brand	Non-Preferred Generic
Abilify Discmelt	aripiprazole ODT
Actiq Lozenge	fentanyl citrate lozenge
Adderall XR	amphetamine Salt Combo ER
Aggrenox	aspirin-dipyridamole ER
Alphagan P	brimonidine P
Androgel	testosterone
Avelox	moxifloxacin
Bactroban Cream	mupirocin Cream
Benzaclin	clindamycin/benzoyl Peroxide
Butrans	buprenorphine
Catapres-TTS	clonidine patches
Cipro Suspension	ciprofloxacin suspension
Derma-Smoothe FS	fluocinolone 0.01% oil
Differin	adapalene
Diovan	valsartan

Preferred Brand	Non-Preferred Generic
Diastat Accudial/Pedi System	diazepam rectal/system
Emend	aprepitant
Evista	raloxifene
Exelon Patch	rivastigmine patch
Exforge	amlodipine / valsartan
Exforge-HCT	amlodipine / valsartan / HCT
Focalin / Focalin XR	dexmethylphenidate
Gabitril	tiagabine
Glyset	miglitol
Hepsera 10 mg	adefovir
Invega ER	paliperidone ER
Kapvay	clonidine ER
Lovenox	enoxaparin
MetroCream	metronidazole cream
MetroLotion	metronidazole lotion
Metrogel Topical	metronidazole gel topical
Methylin Solution	methylphenidate solution
Namenda Solution	memantine solution
Natroba	spinosad
Nexium RX	esomeprazole
Nuvigil	armodafinil
Orapred ODT	prednisolone ODT
Oxycontin	cxycodone ER
Patanase	olopatadine
Provigil	modafinil
Pulmicort respules	budesonide respules
Renvela powder pkt	sevelamer powder pkt
Retin-A Cream/Gel	tretinoin cream/gel
Rythmol SR	propafenone SR
Seroquel XR	quetiapine
Strattera	atomoxetine
Suprax Susp	cefixime Susp
Symbyax	olanzepine / fluoxetine
Tamiflu	oseltamivir
Tegretol Tab/ Susp /XR	carbamazepine Tab/ Susp / XR
TobraDex Drops	tobramycin / dexamethasone drops
Vigamox	moxifloxacin
Vivelle-Dot Patch	estradiol patch
Voltaren Gel	diclofenac gel
Zetia	ezetimibe

Influenza Vaccine and Reimbursement Guidelines for 2017-2018 for N.C. Medicaid

Effective Jan. 1, 2016, N.C. Medicaid will reimburse pharmacies for covered vaccines, including influenza vaccines, as permitted by G.S. 90-85.15B, when administered to N.C. Medicaid beneficiaries 19 years of age and older by an immunizing pharmacist.

Table 1
Influenza Virus Vaccine Billing Codes to be used by Pharmacist for N.C. Medicaid Beneficiaries 19 Years of Age or Older

The CG modifier must be appended to every vaccine and vaccine administration CPT code used to bill vaccines by pharmacists. The CG modifier identifies a pharmacy provider in NCTracks for vaccine claims billing purposes.

Vaccine CPT Code to Report	CPT Code Description
90630CG	Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, for intradermal use
90656CG	Influenza virus vaccine, trivalent (IIV3), split virus, preservative free, 0.5 mL dosage, for intramuscular use
90658CG	Influenza virus vaccine, trivalent (IIV3), split virus, 0.5 mL dosage, for intramuscular use
90674CG	Influenza virus vaccine, quadrivalent (IIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use
90686CG	Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, 0.5 mL dosage, for intramuscular use
90688CG	Influenza virus vaccine, quadrivalent (IIV4), split virus, 0.25 mL dosage, for intramuscular use

The composition of the trivalent influenza vaccines for the 2017-2018 influenza season is:

- A/Michigan/45/2015 (H1N1) pdm09-like virus,
- A/Hong Kong/4801/2014 (H3N2)-like virus,
- B/Brisbane/60/2008-like (B/Victoria lineage) virus.

The quadrivalent influenza vaccines will contain these vaccine viruses and a B/Phuket/3073/2013-like (B/Yamagata lineage) virus.

Details on the 2017-2018 influenza vaccine can be found on the Centers for Disease Control (CDC) Flu Season web page.

FluMist Quadrivalent (LAIV4) should not be used during the 2017-18 season due to concerns about its effectiveness against influenza A(H1N1) pdm09 viruses in the United States during the 2013-14 and 2015-16 influenza seasons.

N.C. Division of Medical Assistance (DMA) does not expect that providers will be vaccinating beneficiaries with the 2017-2018 influenza season's vaccine after date of service June 30, 2018.

Influenza vaccine and administration fee rates for pharmacists are the same as for other providers; refer to the Physician's Drug Program fee schedule on DMA's Fee Schedule web page and Physician Services Fee Schedule web page.

Refer to the tables below for the appropriate CPT billing codes.

Table 2 *Vaccine Administration Billing Codes to be used by Pharmacists for N.C. Medicaid Beneficiaries 19 Years of Age and Older*	
CPT Code(s)	**CPT Code Description**
90471CG	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); **one vaccine** (single or combination vaccine/toxoid)
90472CG (add-on code)*	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); **each additional vaccine.** (Separately list the add-on code(s) for each additional single vaccine and/or combination vaccine/toxoid administered, in addition to the primary procedure)

The CG modifier must be appended to every vaccine and vaccine administration CPT code used to bill vaccines by pharmacists. The CG modifier identifies a pharmacy provider in NCTracks for vaccine claims billing purposes.

*Providers **may** bill more than one unit of 90472 as appropriate.

Detailed information about the regulations regarding pharmacist immunization can be found at Pharmacist Administrated Vaccine and Reimbursement Guidelines published on the October 2016 Medicaid Bulletin.

NDC's Change Each Year for Influenza Vaccines

Providers are required to use appropriate National Drug Codes (NDCs) that correspond to the vaccine used for administration and corresponding CPT code.

Influenza vaccines are licensed each year with new NDCs, so it is important to report the correct code for the products being used to avoid having claims deny with edit 00996 (Mismatched NDC). This will require the claim to be resubmitted with the correct NDC. Below are the influenza vaccine procedure (CPT) codes and corresponding NDCs that should be used for the 2017-2018 influenza season:

Table 1 *CPT and NDC codes for the 2017-2018 Covered Influenza Vaccine Products*	
CPT Codes	**NDC codes**
90630	Fluzone Intradermal Quadrivalent: 49281-0712-40, 49281-0712-48
90656	Afluria: 33332-0017-01, 33332-0017-02 Fluvirin: 70461-0120-02, 70461-0120-12
90658	Afluria: 33332-0117-10, 33332-0117-11 Fluvirin: 70461-0120-10, 70461-0120-11
90674	Flucelvax Quadrivalent:70461-0201-01, 70461-0201-11
90686	Afluria Quadrivalent: 33332-0317-01, 33332-0317-02 Fluarix Quadrivalent: 58160-0907-41, 58160-0907-52 FluLaval Quadrivalent: 19515-0912-41, 19515-0912-52 Fluzone Quadrivalent: 49281-0417-10, 49281-0417-50, 49281-0417-58, 49281-0417-88
90688	Afluria Quadrivalent: 33332-0417-10, 33332-0417-11 FluLaval Quadrivalent: 19515-0896-01, 19515-0896-11 Fluzone Quadrivalent: 49281-0627-15, 49281-0627-78

Procedures for Prior Authorization of Synagis for Respiratory Syncytial Virus Season 2017/2018

The clinical criteria used by N.C. Medicaid for the 2017/2018 Respiratory Syncytial Virus (RSV) season are consistent with guidance published by the *American Academy of Pediatrics (AAP): 2015 Report of the Committee on Infectious Diseases, 30th Edition*. This guidance for Synagis use among infants and children at increased risk of hospitalization for RSV infection is available online by subscription. The coverage season is Nov. 1, 2017, through March 31, 2018. Providers are encouraged to review the AAP guidance prior to the start of the RSV season. Early and Periodic Screening, Diagnosis and Treatment (EPSDT) criteria are evaluated for Synagis requests.

Guidelines for Evidenced-Based Synagis Prophylaxis

- Infants younger than 12 months at start of season with a diagnosis of:
  - Prematurity - born before 29 weeks 0 days gestation
  - Chronic Lung Disease (CLD) of prematurity (defined as birth at less than 32 weeks 0 days gestation and requiring greater than 21 percent oxygen for at least 28 days after birth),
  - Hemodynamically significant acyanotic heart disease, receiving medication to control congestive heart failure, and will require cardiac surgical procedures
  - Moderate to severe pulmonary hypertension.

  Note: Infants with cyanotic heart disease may receive prophylaxis with cardiologist recommendation.

- Infants during first year of life with a diagnosis of:
  - Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways.

- Infants less than 24 months of age with a diagnosis of:
  - Profound immunocompromise during RSV season
  - CLD of prematurity (see above definition) and continue to require medical support (supplemental oxygen, chronic corticosteroid or diuretic therapy) during the six-month period before start of second RSV season
  - Cardiac transplantation during RSV season

Prior Approval Request

During the Synagis coverage period, submit all prior approval (PA) requests electronically to www.documentforsafety.org. The web-based program will process PA information in accordance with the guidelines for use. A PA request can be automatically approved based on the information submitted. The program allows a provider to self-monitor the status of a request. Up to five doses can be approved for coverage. Coverage of Synagis for neuromuscular disease or congenital anomaly that impairs ability to clear respiratory secretions from the upper airway will terminate when the beneficiary exceeds 12 months of age. Coverage of Synagis for CLD, profound immunocompromise, or cardiac transplantation will terminate when the beneficiary exceeds 24 months of age.

Dose Authorization

Each Synagis dose will be individually authorized to promote efficient product distribution. Providers must submit a "**next dose request**" to obtain an authorization for each dose. Providers should ensure the previously obtained supply of Synagis is administered before submitting a next dose request. Providers will fax each single-dose authorization to the pharmacy distributor of choice.

If an infant received one or more Synagis doses prior to hospital discharge, the provider should indicate, as part of the request, the most recent date a dose was administered. The number of doses administered by the provider should be adjusted accordingly. If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, coverage of Synagis will be discontinued.

Pharmacy Distributor Information

Single-dose vial specific authorizations, not to exceed the maximum number of doses approved for the beneficiary, will be issued by N.C. Medicaid. It is important for the Synagis distributor to have the appropriate single-dose authorization on

hand and a paid point of sale (POS) claim prior to shipping Synagis. An individual dose authorization is required for each paid Synagis claim. The drug quantity submitted on the claim must not exceed the quantity indicated on the authorization. Payment for a Synagis claim will be denied if a dose request was not done by the provider. **Use of a point of sale PA override code is not allowed**.

Synagis claims processing will begin on Oct. 26, 2017, to allow sufficient time for pharmacies to provide Synagis by Nov. 1, 2017. Payment of a Synagis claim with a date of service before Oct. 26, 2017, and after March 31, 2018, is not allowed. POS claims should not be submitted by the pharmacy distributor prior to the first billable date of service for the season.

Pharmacy providers should always indicate an accurate days' supply when submitting claims to N.C. Medicaid. Claims for Synagis doses that include multiple vial strengths must be submitted as a single compound-drug claim. Synagis doses that require multiple vial strengths that are submitted as individual claims will be subject to recoupment. Physicians and pharmacy providers are subject to audits of beneficiary records by N.C. Medicaid. Maintain Synagis dose authorizations in accordance with required recordkeeping time frames.

Provider Information

Providers without internet access should contact the N.C. Medicaid Outpatient Pharmacy Program at 919-855-4300 to facilitate submission of a PA request for Synagis. More information about the Synagis program is available at www.documentforsafety.org.

Submitting a Request to Exceed Policy

The provider should use the *Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age* to request Synagis doses exceeding policy or for coverage outside the defined coverage period. **Fax the form to 919-715-1255.** The form is available on the NCTracks Prior Approval web page. Information about EPSDT coverage is found on Medicaid's Health Check and EPSDT web page.

Technical Support

Technical support is available Monday to Friday from 8 a.m. to 5 p.m. by calling 1-855-272-6576 (local: 919-926-3986). Technical support can assist with provider registration, user name and password issues, beneficiary searches, and other registry functions.

How to Submit a "High Dose" Opioid Pharmacy Prior Approval

Effective Aug. 27, 2017, PA is required for opioid analgesic doses that **exceed 120mg of morphine or equivalent doses per day**.

Remember when entering a PA request for opioids, question No. 3 is referring to all opioid products combined that the beneficiary is receiving. If the total daily dose is equal to or greater than 120mg of morphine equivalents per day, a high dose PA is required.

> ***Question No. 3: Is the requested daily dose in combination with other concurrent opioids less than or equal to 120mg of morphine or an equivalent dose?***

To request a high dose PA, question No. 3 must be marked as "no" (which indicates the beneficiary is exceeding 120mg of morphine equivalents per day) and subsequent drop- down fields populated with beneficiary's diagnosis and estimated length of time the beneficiary will be exceeding dose limits.

The provider can review the beneficiary's opioid medication history in the provider portal, which may provide assistance in determining the beneficiary's total daily opioid dose. See the below link for assistance in using this feature.

Medication History Response Job Aid

North Carolina Medicaid and North Carolina Health Choice Statement Concerning Prior Approval Requirements for Opioid Prescriptions

North Carolina is facing an opioid epidemic. Three North Carolinians die from an opioid-related overdose every day. Modifying clinical coverage policies to promote safe opioid prescribing is an essential and significant step to realize the vision of the North Carolina Opioid Action Plan to reduce opioid deaths by 20 percent by 2021. On Aug. 27, 2017, prior approval became effective for Medicaid and NC Health Choice opioid prescribed analgesic doses that exceed 120mg of morphine equivalents per day; are greater than a 14-day supply of any opioid; or are non-preferred opioid products on the North Carolina Medicaid Preferred Drug List. The Department of Health and Human Services (DHHS) worked closely with prescribing physicians and pharmacists to develop the best approach to reduce the oversupply of prescription opioids available for diversion and misuse, promote safe opioid prescribing for patients, and encourage alternative pain management, while minimizing administrative requirements as much as possible.

Opioid Prescriptions: Emergency Supply and Partial Fill

As a reminder, pharmacy providers may use the 72-hour emergency supply allowed for drugs requiring prior approval. Federal law requires that this emergency supply be available to Medicaid beneficiaries for drugs requiring prior approval (Social Security Act, Section 1927, 42 U.S.C. 1396r-8(d)(5)(B)). Use of this emergency supply will allow access to medically necessary medications until prior approval is obtained or a revised opioid prescription not requiring prior approval is received.

As an additional reminder, the Comprehensive Addiction and Recovery Act of 2016 (CARA), and the rules and regulations of the NC Board of Pharmacy, allow a North Carolina licensed pharmacy to provide a partial fill of a Schedule II controlled substance prescription when the prescription is written and filled in compliance with federal and state law, the partial fill is requested by the patient or the prescriber and the total quantity dispensed in all partial fills does not exceed the total quantity prescribed. The total amount of a Schedule II controlled substance prescription may be filled no later than 30 days from the date of the prescription.

If a pharmacist receives a verbal Schedule II controlled substance prescription pursuant to an emergency, the pharmacist may provide a partial fill, but must provide the remainder of the prescription amount within 72 hours. After 72 hours, no further dispensing on the emergency prescription is allowed. All other requirements regarding the need to receive a hard copy (or valid electronic) prescription within seven days remain. More information is found here: http://www.ncbop.org/faqs/Pharmacist/faq_SchIIControlledSub.htm.

DHHS appreciates the partnership of prescribing physicians and pharmacists to combat the opioid crisis in North Carolina and to keep our fellow North Carolinians safe. Opioid safety and alternative pain management provider resources are available on the Medicaid Outpatient Pharmacy website and the Community Care of North Carolina Medicaid Opioid Safety Resources website.

(Reprinted from the N.C. Board of Pharmacy)

72-hour Emergency Supply Available for Pharmacy Prior Authorization Drugs

Pharmacy providers are encouraged to use the 72-hour emergency supply allowed for drugs requiring PA**. Federal law requires that this emergency supply be available to Medicaid beneficiaries for drugs requiring PA** (Social Security Act, Section 1927, 42 U.S.C. 1396r-8(d)(5)(B)). Use of this emergency supply will ensure access to medically necessary medications.

The system will bypass the PA requirement if an emergency supply is indicated. Use a "**3**" in the Level of Service field (418-DI) to indicate that the transaction is an emergency fill.

Note: Copayments will apply and only the drug cost will be reimbursed. There is no limit to the number of times the emergency supply can be used.

5. Durable Medical Equipment and Supplies, and Orthotics & Prosthetics (DMEPOS)

1. Clinical Coverage Policies 5A-1, 5A-2, 5A-3 and 5B have been amended to comply with the CMS Home Health Final Rule – 42 CFR, Part 440.70. The updated policies were posted and became effective July 1, 2017. Here is a summary of the updates:
    - Definitions of medical equipment and supplies were updated to match the final rule language;
    - Documentation of a face-to-face encounter between the beneficiary and prescribing practitioner within 6mos of the initiation of the primary reason for DMEPOS services was added to coverage criteria;
    - A review of DMEPOS services by the prescribing practitioner at least annually was added to coverage criteria;
    - Language was added to indicate that DMEPOS could be covered for any non-institutional setting in which normal life activities take place;
    - Language restricting coverage of DMEPOS items for use in the home only was deleted;
    - References to coverage being limited to only items listed in the fee schedules were deleted.

2. Clinical Coverage Policies 5A-1, 5A-2, 5A-3 were updated to clarify compliance with the CMS Home Health Final Rule – 42 CFR, Part 440.70. Language referencing how medical necessity reviews for items not listed in policy or the corresponding fee schedule could be requested for adult beneficiaries was added in multiple locations throughout the policies. A step-by-step procedure was added as a new attachment. These policies were posted for 30-day public comment on Oct. 27, 2017.

6. Outpatient Specialized Therapies

- **10-A, Outpatient Specialized Therapies** was a Non-PAG revision implemented:
    - 10/1/2017 - Clarify annual and episodic therapy visits and adjust specified time frames to request prior approval for therapy
        - Currently those with appropriate diagnosis or who have received surgery can receive physical therapy, but only if prior approval is requested within the appropriate timeframe, as determined by diagnosis or surgery type. This revision expands the timeframe for prior approval, not the number of therapy visits. Previously, the timeframe to request prior approval left beneficiaries with longer than expected recovery times unable to receive therapy, due to the expired time frame.
    - 10/15/2017 - Removed end-dated ICD-10-CM Codes
        - The following ICD-10-CM codes were end dated and removed from CCP 10A:

I60.2	I60.22	I69.21
I60.20	I69.01	I69.31
I60.21	I69.11	I69.81
		I69.91

- **10-C, Outpatient Specialized Therapies** was a PAG revision not yet implemented:
    - The policy was revised to more closely align to CCP 10A and CCP 10B.
        - The addition of the new occupational therapy evaluation and re-evaluation codes (97165, 97166, 97167 and 97168) and physical therapy evaluation and re-evaluation codes (97161, 97162, 97163 and 97164) that were implemented 1-1-2017 must be included in the policy.
        - Removed from policy, "Assessment services are billable only for students receiving assessment services prescribed through an IEP. Initial assessments conducted to identify students for Special Education Services are only reimbursable from Medicaid after the development of an IEP that lists the service as being needed by the beneficiary. If the assessment does not reveal “medical necessity” for the services, the assessment cannot be billed. "

- Evaluation services, when administered by a licensed professional, regardless of outcome, should be billable for Medicaid beneficiaries.
- The policy was approved by the Physician Advisory Group (PAG) at the July 27th meeting and was posted for 45-day public comment. The policy will be implemented in the first quarter of 2018.

7. Home Care Services

Private Duty Nursing Services (PDN)

DMA revised the PDN Clinical Coverage Policies 3G-1 & 3G-2:

- **3G-1, Private Duty Nursing for Beneficiaries 21 Years of Age and Older**
  - Prior authorization (PA) certification period extension: PA certification periods will be extended to 6 months instead of 60 days. Documentation for reauthorization shall be submitted 30 days prior to the end of the current approved certification period – this will include the signed CMS-485 Plan of Care.

- **3G-2: Private Duty Nursing for Beneficiaries Under 21 Years of Age**
  - PDN and schools: Clarification of how and when providers are to document nursing in school, how PDN services in the home will be covered when beneficiary is out of school, and new documentation that will be help capture this information (Verification of School Nursing form).
  - Congregate care: Expansion of definition to include the maximum ratio of beneficiaries to private duty nurse and specific billing codes that will indicate whether a RN or LPN is providing the congregate care.
  - Prior authorization (PA) certification period extension: PA certification periods will be extended to 6 months instead of 60 days. Documentation for reauthorization shall be submitted 30 days prior to the end of the current approved certification period – this will include the signed CMS-485 Plan of Care.

Hospice

Hospice Payment Reform

Effective October 29, 2017, the NC Department of Health and Human Services (DHHS) will implement Hospice Payment Reform in NCTracks based on guidance from the Centers for Medicare and Medicaid Services (CMS). The reform consists of service intensity add-on (SIA) payments for Hospice social worker (SW) and registered nurse (RN) visits provided during the last 7 days of life when provided during routine home care. Payment reform also includes the implementation of two routine home care rates, paying a higher rate in the first 60 days of a Hospice election and a lower rate for days 61 and later, based on paid claims history. This two-tiered rate calculation is effective for dates of service on and after January 1, 2016. This was first announced in the January 2016 Medicaid Special Bulletin.

- Specific payment rules apply for patients discharged from Hospice within the first 60 days and later readmitted. Note the two-tier pricing and discharge rules are recipient specific. Change in Hospice provider does not impact pricing.
- Claims that are billed out of sequence and are determined to have overpaid based on subsequent claim receipts for prior dates of service may be voided. Providers will be responsible for resubmission.
- Among the changes associated with Hospice Payment Reform and directly related to the SIA payment, is the discontinuation of bill status code 20 to denote the death of a Hospice patient. In keeping with Medicare guidelines, Hospice claims must bill using a Hospice specific patient status code when the patient has expired. Effective October 29, 2017, valid discharge codes denoting death of the patient for Hospice claims are:
  - 40 - Expired at home
  - 41 - Expired at medical facility
  - 42 - Expired place unknown

Note: the 7-day service intensity add-on must be billed on the same claim that is denoting the patient expiration status code.

These changes are specific to Medicaid primary claims. Hospice claims paid with a date of service on or after January 1, 2016, and processed before October 29, 2017, will be reprocessed at a later date.

8. Behavioral Health IDD Section Updates:

Treatment for Autism Spectrum Disorder:

The draft State Plan Amendment (SPA) has been complete and was submitted to CMS. DMA responded to formal request for additional information on 11/17/17.

TBI Waiver:

DMA responded to a formal request for additional information from CMS on the TBI waiver specifically regarding the Home and Community Based Standard (HCBS) process and ensuring that all potential sites are fully compliant with CMS's Final HCBS rule. Corrections have been provided to CMS.

Innovations Waiver:

DMA in the process of completing the 1915 (c) NC Innovations waiver renewal. Meetings with the NC Innovations State Stakeholder group were held to discuss feedback gathered from listening sessions and webinars. A draft waiver will be posted to the DMA website for public comment as soon as it's available.

Behavioral Health Clinical Policy Updates:

Services for Substance Use Disorders:

DMA completed listening sessions across North Carolina and gathered substantial feedback from stakeholders. This provided DMA with invaluable information pertaining to stakeholder perceptions of and recommendations for the substance use disorder service array. The service array was found to be comprehensive, including Medicaid services as well as state-funded services provided through DMH. DMA has identified several services that are not Medicaid services and is working with CMS on adding those services to the 1115 waiver as well as to as to our current state plan. In addition, DMA and DMH are planning updates to selected substance use disorder policies. The first two of these policies for revision are Substance Abuse Intensive Outpatient Program (SAIOP) and Substance Abuse Comprehensive Outpatient Treatment (SACOT).

Critical Access Behavioral Health Agencies (CABHA)

The special provision submitted to the legislature to remove CABHA from statute was not acted upon and it is unknown when this will occur. Thus, CABHA remains in statute, the state plan, and policy until further notice.

Psychosocial Rehabilitation (PSR)

DMA held listening sessions across the state for PSR and received excellent feedback from MCOs as well as PSR providers. DMA researched evidence-based models of this service and found that the evidence is for Psychiatric Rehabilitation (PR) services. Based on feedback from stakeholders and, in collaboration with the MCOs, DMA has revised the current PSR policy so that it aligns more closely to the evidence-based practice of Psychiatric Rehabilitation. This policy is now ready for review by DMH prior to being shared with stakeholders via public comment.

Mobile Crisis Management (MCM)

DMA gathered feedback from providers of MCM as well as MCOs to understand stakeholder perceptions of this service and to solicit their recommendations for revising the service. This resulted in DMA receiving feedback from stakeholders with detailed recommendations for modifying the service. DMA and DMH participated in a two-day training on children and adolescent mobile crisis and outreach services and this resulted in a pilot program that is in the process of being implemented in North Carolina. This training also provided conceptual and practical feedback applicable to services to adults. DMA has revised the current MCM service considering the

feedback from stakeholders as well as the research on best practices for MCM. This revision will be finalized internally at DMA and then shared with other stakeholders via public comments.

Community Support Team (CST)
DMA and DMH/DD/SAS are in the process of updating the CST policy to add additional emphasis on therapeutic interventions and permanent supportive housing. With these additions to CST, the plan is to not have an additional separate Transition Management Services policy. Although the plan is to only amend CST, it will require a change to the State Plan; both clinical and fiscal. The draft clinical policy has been completed. DMA is in the process of working with Provider Reimbursement to determine the rate for this amended service.

LME-MCO Contract Section Updates:

External Quality Review
DMA continues to work on the SFY 17/18 External Quality Reviews (EQR) for each LME-MCO. EQRs focus on quality, timeliness, and access to the health care services that an LME-MCO furnishes to Medicaid beneficiaries. Trillium, Vaya, Sandhills Center, Partners and Eastpointe have been completed. Cardinal and Alliance will have their reviews in October, December and January, respectively.

1915 (b) Waiver
DMA has begun work on the 1915 (b) waiver renewal. The current waiver expires on July 31, 2018. Listening sessions have been held to solicit stakeholder feedback. A draft waiver will be posted to the DMA website for public comment as soon as it's available.

Community Behavioral Health Service Needs, Providers and Gaps Analysis:
Letters were sent to the LME-MCOs at the beginning of November as follow up to their 2017 *Community Needs Assessment and Gaps Analysis*. Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMH/DD/SAS) and the Division of Medical Assistance (DMA) reviewed for level of service availability, choice of providers, identified community needs/service gaps in service, and plans to address those needs. Five of the reports were approved as submitted having shown sufficient compliance. The other two were approved upon receipt of clarifying information.

Changes have been made to the 2018 analysis requirements which include:

- clarification of geographic, cultural and special population groups;
- guidance on seeking input from system partners, stakeholders and families;
- reporting requirements on In Lieu of (Medicaid) and Alternative (non-Medicaid) Services; and
- reporting requirements on Transitions to Community Living Initiative (TCLI) and Children with Complex Needs.

A bulletin will be coming out soon to update the LME-MCO's on these requirements. LME-MCO's will have the opportunity to submit questions and a webinar will be held in December on the new requirements The SFY 2018 gaps analysis report will be due on June 1, 2018.

9. Long Term Services and Reports

Community Alternatives Program for Children (CAP/DA)

The § 1915 (c) Home and Community-Based Services Waiver for the Community Alternatives Program for Disabled Adults (CAP/DA) is scheduled to expire on Sept. 30, 2018. The N.C. Division of Medical Assistance (DMA) must submit a waiver renewal application to the Centers for Medicare & Medicaid Services (CMS) no later than June 1, 2018, 90 days prior to the expiration of the waiver, to ensure the continuation of the waiver. In addition to the waiver renewal application, the Clinical Coverage Policy, 3K-2, Community Alternatives program for Disabled Adults (CAP/DA), will be revised to support the clinical operation of CAP/DA.

To initiate the planning activities for the expiring waiver, stakeholder engagement listening sessions were held in the months of October and November 2017. There was a total of five (5) listening sessions across North Carolina

and a total of 228 attendees. To assist with the design of the CAP/DA waiver, four (4) focus groups will convene to discuss areas of quality assurance, eligibility, home and community-based services and case management. The kick-off date of the focus groups is scheduled for Nov. 29, 2017 with regularly scheduled meetings starting on Dec. 11, 2017 – Mar. 2, 2018.

The CAP/DA waiver is currently supporting 10,490 individuals to live safely in their home communities. There are 222 individuals assigned an Alzheimer's slot, a targeted group appropriated through Session Law 2016-94, Section 12H.5. There are 1932 individuals waiting for services on a county based waitlist.

Community Alternatives Program for Children (CAP/C)

To continue stakeholder engagement to assess the progress of the CAP/C waiver since implementation in March 2017, a stakeholder listening session was held in person and by conference on Oct. 19, 2017 in Raleigh, N.C. A total of 83 individuals participated. From that session, a workgroup was organized to discuss a streamline approach in evaluating the need for specific waiver services such as modifications and technologies.

CAP/C is currently supporting 2,434 individuals to live in their home communities. Currently, a total of 230 individuals are participating in the consumer-directed model of care.

Personal Care Services (PCS)

SPA 17-0009 was submitted to CMS on September 20, 2017 requesting a PCS rate increase. This state plan amendment increases the Personal Care Services to three dollars and eighty-eight cents (3.88) effective August 1, 2017. Beginning January 1, 2018, the rate shall increase to ($3.90) the rate paid per 15-minute billing unit for personal care services provided pursuant to Clinical Coverage Policy 3L.

Human Immunodeficiency Virus (HIV) Case Management

Clinical coverage policy 12B, Human Immunodeficiency Virus (HIV) Case Management, was posted for public comment 9/6/2017 – 10/15/2017. Policy posting is awaiting SPA approval from CMS. DMA plans to submit amended SPA to CMS on or before January 1, 2018. The state plan change will carve out non-essential language in the SPA that is reflected in the Clinical Coverage Policy 12B for HIV Case Management and to reflect changes made to provider requirements. Provider requirement changes are as follows:

- Annual Case Manager Training Requirements (Reduced from 20 hours to 12 hours annually)
- Reduced number of quality assurance visits during first year of certification (reduced from 4 visits to two visits).
- Removed provider requirement to secure a performance bond (no current rule that reflects this as a provider requirement).
- Specified that a physician or attending practitioner can provide a written order for the initiation of services however, ongoing case management services beyond two calendar months require a written order from the beneficiary's primary care physician.

Changes to provider requirements reflect feedback received during stakeholder engagement, research of other state's administration of HIV Case Management Services, as well as a review of clinical policy's ability to effectively monitor and provider oversight of program requirements.

Program of All Inclusive Care for the Elderly (PACE)

The Division of Medical Assistance is required to submit a report to the Joint Legislative Oversight Committee on Medicaid and NC Health Choice on the efficacy of the PACE Program, no later than March 1, 2018.. Listening Sessions were held to obtain feedback on the PACE program from stakeholders and the general public in Charlotte on October 26, Fayetteville on November 2, and Pittsboro on November 6.

10 Medical Health

New or Amended Policies Posted

1A-30, Spinal Surgery

The Division of Medical Assistance (DMA) posted policy 1A-30 on 9/1/17, adding prior approval requirements to 87 surgical procedures per Session Law 2011-145 HB 200 Section 10.37(a)(11)(g)(4). The policy also lists diagnoses that are exempt based on the emergent nature of the surgery.

1S-8, Drug Testing for Opioid Treatment and Controlled Substance Monitoring

Policy 1S-8 outlines medical necessity, frequency, and annual limits of drug testing for substance use disorders and chronic pain management. The purpose of this policy is to allow for quality care while limiting overutilization of testing that is designed to be one of many tools used to assess the beneficiary's response to treatment. Recent data analysis indicates approximately the top 1% of beneficiaries receiving drug tests account for 17% of the total tests ordered.

1G-2, Skin Substitutes

The policy was amended to add definitions and additional documentation requirements. The coverage text was updated to include an ankle-brachial index (ABI) of greater than or equal to 0.70. EpiFix (Q4131), a new skin substitute, was added for new coverage for venous stasis ulcers and diabetic foot ulcers.

1-I, Dietary Evaluation and Counseling and Medical Lactation Services

Clinical Coverage Policy 1-I, Dietary Evaluation and Counseling and Medical Lactation Services was updated, effective Dec. 1, 2017.

Medical lactation services covered in CCP 1-I include lactation evaluation and breastfeeding counseling when the breastfeeding infant has a chronic, episodic, or acute condition for which medical lactation services are a critical component of medical management.

Beginning Dec. 1, 2017, three new codes (96150, 96151, 96152) are available when an International Board Certified Lactation Consultant (IBCLC) provides medical lactation support. These codes require modifier SC when billed for Medical Lactation support services and are billed under the infant's MID. The initial lactation assessment (96150-SC) is allowed only once per beneficiary lifetime. Lactation support services (any combination of 96150-96152 with modifier SC) are limited to a total of six units per single date of service. In addition, lactation support services (any combination of 96150-96152 with modifier SC) are limited to a total of 36 units per beneficiary lifetime.

Medical lactation services can be billed by physicians, certified nurse midwives, nurse practitioners, and physician assistants. Health departments who employ one of these providers or an IBCLC may bill for medical lactation services. Rural health centers and federally qualified health centers will bill medical lactation provided by an IBCLC as part of a core service.

ENROLLMENT EXEMPTION FOR RESIDENTS AND INTERNS

DMA will continue to utilize the NPI Exemption List in NCTracks which allows residents and interns enrolled in Graduate Dental and Medical programs and Area Health Education Centers to be exempt from the provider enrollment requirement only through Jan. 31, 2018. The exemption from the provider enrollment requirement does not include an exemption from the DEA registration requirement for controlled substances.

This exemption list is only applicable to the prescribing provider on a pharmacy claim. All providers that meet the enrollment criteria are required to enroll.

MEDICAID REQUIRED ENROLLMENT FEE

The N.C. Medicaid and N.C. Health Choice (NCHC) application fee is $100, which covers costs associated with processing enrollment applications. The $100 application fee is required for both in-state and border-area (within 40 miles) providers during initial enrollment and when providers complete the five-year re-verification process.

In addition, some providers are required to pay the Affordable Care Act (ACA) application fee. These providers are defined in federal regulation at 42 CFR 455.460, and in N.C. General Statute 108C-3 (e) and (g) as moderate- or high-risk. The ACA application fee is $560 for calendar year 2017, and may be adjusted by the Centers for Medicare and Medicaid Services (CMS) annually. This fee covers the costs associated with provider screening during the enrollment process. The application fee will be collected during initial enrollment, adding a new site location, re-enrollment, and five-year reverification. Currently the fee collection is a manual process. On Jan. 28, 2018, system modifications in NCTracks will automate the fee collection for a more efficient processing time for enrollment, re-enrollment, managed change requests, and reverification applications.