WRITTEN SECTION REPORTS

REPORT PERIOD SEPTEMBER 1, 2021 THROUGH NOVEMBER 30, 2021

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

The Pharmacy & Therapeutic Committee met on 09/14/2021, 10/12/2021, and 11/09/2021
The N.C. Physician Advisory Group met on 09/23/2021, and 10/28/2021

Recommended Pharmacy

- Prior Approval Criteria- Medications for Duchenne's Muscular Dystrophy- 09/23/2021
- Prior Approval Criteria- Opioid Analgesics- 09/23/2021
- Prior Approval Criteria- PCSK9 Inhibitors- 09/23/2021
- Lock-In-10/28/2021
- Prior Approval Criteria- Anti-Narcolepsy Medications- 10/28/2021
- Prior Approval Criteria- Continuous Glucose Monitors- 10/28/2021
- Annual/Semi-Annual Preferred Drug List Changes-10/28/2021
- Prior Approval Criteria- Epidiolex- 11/09/2021 P&T
- Behavioral Health Clinical Edits-11/09/2021 P&T
- Prior Approval Criteria- Migraine Calcitonin Gene Related Agents-11/09/2021 P&T
- Prior Approval Criteria- Topical Anti-Inflammatory Agents-11/09/2021 P&T

Recommended Clinical Coverage Policies

- 1E-6 Pregnancy Management Program - 10/28/2021
- 8A-10 Clinically Managed Withdrawal Services (New Policy) - 10/28/2021

PAG Notifications

PAG was notified of the following pharmacy updates:

- Ivermectin: NC Medicaid notified PAG that prior authorization will be required for ivermectin. The only criterion will be that the patient has a parasitic infection. Many individuals have been seeking ivermectin treatment for covid-19.
- Regeneron subcutaneous injection: NC Medicaid informed PAG about a new initiative to cover at retail pharmacies subcutaneous Regeneron for post-exposure prophylaxis for individuals thought to have high risk for severe COVID. The treatment can be provided under a state standing order from Dr. Betsey Tilson, State Health Director. Payment will be $450 for the injection while the federal government pays for the medication, a combination of 2 monoclonal antibodies that target the coronavirus spike protein.

2. Pharmacy Items Posted for Public Comment

- Prior Approval Criteria- Aduhelm -10/12/2021-11/26/2021
- Prior Approval Criteria- Cystic Fibrosis Medications -10/12/2021-11/26/2021
- Prior Approval Criteria- Hepatitis C Medications -10/12/2021-11/26/2021
- Prior Approval Criteria- Zolgensma -10/12/2021-11/26/2021
- Prior Approval Criteria- Medications for Duchenne's Muscular Dystrophy -10/12/2021-11/26/2021
- Prior Approval Criteria- Opioid Analgesics -10/12/2021-11/26/2021
- Prior Approval Criteria- PCSK9 Inhibitors -10/12/2021-11/26/2021
- Lock-In - 11/03/2021-12/18/2021
- Prior Approval Criteria- Anti-Narcolepsy Medications -11/03/2021-12/18/2021
- Prior Approval Criteria- Continuous Glucose Monitors -11/03/2021-12/18/2021
- Annual/Semi-Annual Preferred Drug List Changes -11/03/2021-12/18/2021

3. New or Amended Policies Posted to Medicaid Website

- 8C, Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers - 09/01/2021
- 3G-1, Private Duty Nursing for Beneficiaries Age 21 and Older - 09/01/2021
- 11A-17, CAR-T Cell Therapy - 10/01/2021

New or Amended PA Criteria Posted

- Prior Approval Criteria- Ivermectin-09/10/2021
- Prior Approval Criteria- Medications for Duchenne's Muscular Dystrophy - 10/01/2021
- Prior Approval Criteria- Anti-Parkinson's Medications - 10/01/2021
- Prior Approval Criteria- Cystic Fibrosis Medications- 10/01/2021
- Prior Approval Criteria- Epidiolex-10/01/2021
- Prior Approval Criteria- Hepatitis C Medications-10/01/2021
- Prior Approval Criteria- Immunomodulators-10/01/2021
- Prior Approval Criteria- Lupus Medications-10/01/2021
- Prior Approval Criteria- Monoclonal Antibodies-10/01/2021
- Prior Approval Criteria- Neuromuscular Blocking Agents-10/01/2021
- Prior Approval Criteria- PCSK9 Inhibitors-10/01/2021

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

September 2021 – November 2021

Temporary COVID-19 flexibilities previously reported, remain in effect.

Clinical Coverage Policies 5A-1, Physical Rehabilitation Equipment and Supplies and **5B, Orthotics & Prosthetics** and the NC Medicaid State Plan are being amended to allow podiatrists to prescribe DME/POS within their scope of practice as authorized under state law, in alignment with an update to the federal regulations at 42CFR §440.70. The target date for these updates is March 1, 2021.

Clinical Coverage Policy 5A-2, Respiratory Equipment and Supplies is being amended to add coverage for heated tubing used with positive airway pressure device (HCPCS A4604), and water chamber for humidifier used with positive airway pressure device (HCPCS A7046); to increase quantity limits for tracheostomy supplies from four units per year to four units per month (HCPCS A7520, A7521, A7525). In addition, information is being added to indicate that physicians, physician assistants, and nurse practitioners may issue and be reimbursed for asthma supplies E0570, A7003, A7004, A7005, A7006, A7015, A4627 and A4614 without being enrolled as a DME supplier. The targeted effective date for this update is April 1, 2022

Clinical Coverage Policy 5A-3, Nursing Equipment and Supplies is being amended to eliminate the prior authorization requirement for phototherapy (bilirubin) light with photometer (HCPCS E0202) when existing medical necessity criteria are met. The targeted effective date for this update is April 1, 2022. The maximum allowable daily rental reimbursement rate for HCPCS E0202 was increased to align with Medicare, effective August 16, 2021. These updates are intended to help alleviate issues of access for infants in the western region of NC.

5. Outpatient Specialized Therapies/Local Education Agencies (LEAs)

September 2021 – November 2021

Temporary COVID-19 flexibilities previously reported, remain in effect.

6. Long-Term Services and Supports (LTSS)

Community Alternatives Program for Children (CAP/C) 1915(c) Home and Community-based Services (HCBS) Waiver:
NC Medicaid is in the progress of renewing the CAP/C HCBS waiver. The CAP/C waiver will expire on Feb. 28, 2022. At that time, NC Medicaid will send the renewed waiver application to the Centers for Medicare and Medicaid Services (CMS) to request approval of the CAP/C waiver for another five years. The renewal waiver will propose changes to address gaps in service provision, quality improvement in services and providers, and accessibility to waiver slots across the state.

NC Medicaid will propose two significant initiatives to CMS. The first initiative is the opportunity for parents and legally responsible parties to be paid caregivers (a new service called Coordinated Caregiving) when health care professionals are not available to render care. The second initiative is permitting children with skill care needs (similar to children who qualify for private duty nursing) to direct their care through the consumer direction service option included in the CAP/C waiver.

In addition, the unduplicated total participant enrollment count of 4,000 will increase to 6,000 by the fifth year of the renewal waiver period. Lastly, the waiver will also expand the service definitions of coverable waiver services to mitigate infection from viruses and address other social determinants. A stakeholder meeting is scheduled for Dec. 14 to start the public comment period of the proposed CAP/C waiver changes.

Program of All-Inclusive Care for the Elderly (PACE):
The Division of Health Benefits announced the selection of applicants for recommendation to Centers for Medicare and Medicaid Services (CMS) for PACE Service Area Expansion on August 2, 2021. The selection resulted from a Request for Applications (RFA) for the expansion of the Program of All-Inclusive Care for the Elderly (PACE). A recommendation for expansion does not create a contract nor an obligation to fund or implement service area expansion. Selected applicants are permitted to submit a PACE Service Area Expansion Applications to CMS. The applicants selected for recommendation to (CMS) for PACE Service Area Expansion and the status of the organizations application to CMS for Service Area Expansion (SAE) are as follows:

- Pace@Home has submitted their application to CMS for SAE in September. They are adding ten zip codes to their currently serviced counties of Catawba, Lincoln, Burke, Caldwell, and Alexander.
- Pace of the Triad will be building a new PACE center and is not expected to submit their application until March 2022 at the earliest. They are proposing to add Forsyth, Stokes, and Surry counties to their currently serviced counties of Guilford and Rockingham.
- Carolina SeniorCare will be building a new PACE center and is not expected to submit their application until March 2022 at the earliest. They are proposing to add Beaufort, Carteret, Craven, Jones, Lenoir, Onslow, and Pamlico to their currently serviced counties of Rowan, Davidson, Davie, and Iredell.
- Senior Total Life Care will be building a new PACE center and is not expected to submit their application until March 2022 at the earliest. They are proposing to add Rutherford county to their currently serviced counties of Gaston, Cleveland, and Lincoln.

Final approval of expansion is contingent upon CMS approval of the application, completion of the final state readiness review, satisfactory plan to address any outstanding corrective action requests, maintaining a fiscally sound operation as required in 42 CFR 460.80 and the availability of funds for the State Fiscal Year in which expansion is scheduled to take effect.

7. Behavioral Health IDD Section

Treatment for Autism Spectrum Disorder- Revision to increase eligibility so it no longer ends at 22 is in process with CMS. This was also part of the HCBS increased FMAP plan which NC Medicaid is working with CMS on to receive final approval.

TBI Waiver- Waiting for final approval from CMS to renew the TBI Waiver and to expand the waiver to Mecklenburg and Orange Counties as the TBI waiver is currently in Alliance's 4 counties and Alliance will be adding Mecklenburg and Orange Counties to their catchment on 12/1/21. If approved, the TBI Waiver renewal will include lowering the age of injury down to 18 and up (was 22 and up); increasing the federal poverty level limit for participation up to 300%; adding Supported Living and Remote Supports Service Definitions.

Innovations Waiver- 1000 Additional Slots were approved in the recent NC State Budget. NC Medicaid and DMHDDSAS continue to partner to share information and resources on Community Integrated Employment and Supported Employment.

Behavioral Health Clinical Policy Updates:

- CCP 8A-11 Medically Monitored Inpatient Withdrawal Management- policy has been drafted, reviewed by DHB and DMH SMEs, stakeholder work groups have been facilitated, and policy has been shared with EBCI. Policy is scheduled for Nov/Dec PAG
- CCP 8C- policy has been revised to add information regarding ASAM completion requirement and ASAM training requirements, as well as language defining SBIRT and expanding the allowable practitioners for SBIRT to include licensed professionals. Second round of stakeholder work group scheduled for 11/29/2021, anticipating a January 2022 PAG
- CCP 8B Inpatient Behavioral Health Services- policy has been revised to align with 2013 ASAM guidance, reviewed by DHB and DMH SMEs, stakeholder work groups have been facilitated, and policy has been shared with EBCI. Policy is being edited and will either go to Nov/Dec 2021 PAG or January 2022 PAG
- CCP Clinically Managed Population-Specific High Intensity Residential Program policy has been drafted, reviewed by DHB and DMH SMEs, two stakeholder work groups have been facilitated, will facilitate one more work group, anticipate a February 2022 PAG
- CCP Clinically Managed High-Intensity Residential Services Adult & Adolescent- stakeholder engagement groups have been facilitated with adolescent SUD providers and pregnant/parenting women using substances providers.
- CCP Individual Placement and Support- policy has been drafted, reviewed by DHB and DMH SMEs, first stakeholder work group scheduled for 11/19/2021

PROVIDER OPERATIONS REPORT

Provider Operations continues to enhance our operational reports and internal business procedures for a more streamlined Standard Plan (SP) monitoring process. Inbound deliverables remain a part of readiness to ensure all policies are accurate and the provider community is educated appropriately. We are currently collaborating with the DHB training and development team on creating a set of helpful hints and lessons learned about contract management to share with other business units within the division that are still trying to streamline their monitoring oversight processes.

The Tailored Plan (TP) Team is continuing the review cycle for all 30 and 90-day post-contract award inbound deliverables and are finalizing outbound templates to assist the TPs with future submissions. Provider Operations is working cross-functionally with internal Business Units and the Enrollment Broker (EB) to update the Provider Directory to include the TP providers and information about the BH I/DD Tailored Plan. Workgroups have been initiated to develop and analyze TP operational reports, and to finalize the LD/SLA Playbook with the Analytics team. Several TP contract amendments were submitted to ensure the Department remains up to date with the latest Code of Federal Regulation (CFR), as well as CMS, federal, and state regulations; and to more closely align with the Standard Plan contract. Staff meets on a weekly or biweekly cadence with the Tailored Plans to assist with Provider Operations-related questions and issues that arise during Implementation, as well as provide technical support and guidance. The development of Tailored Plan business procedures and monitoring processes has been initiated with guidance and assistance from our Provider Operations Standard Plan partners.

In response to findings cited in the Office of State Auditor (OSA) Performance Audit published February 2021, and Single Audit Report for the year ending June 30, 2020, Provider Operations has submitted several Customer Service Requests (CSRs) to improve the Medicaid and NC Health Choice provider screening, enrollment, and termination processes:

- CSR 2435 implemented October 24, 2021. When re-verification/re-credentialing resumes, Medicaid's Fiscal Agent will conduct primary source verification of all credentials required for enrollment for all individual and organization providers during re-verification/re-credentialing as required in CFR 455.450.
- CSR 2460 is scheduled to implement January 30, 2022. It will require the Fiscal Agent to automate two database searches required during credentialing. This automation will reduce the chance of errors identified in the manual search process.
- CSR 2481 is scheduled to implement April 24, 2022. It will require the Fiscal Agent to implement the first of a two-phased process for ownership and managing employee disclosure screening prior to initial enrollment for in-state organizations. Once phase one is implemented and any unforeseen issues are addressed, Provider Operations will work with the Centers for Medicare & Medicaid Services (CMS) on phase two which will expand the ownership screening process to include in-state, border and out-of-state organization providers during initial enrollment and re-verification. We anticipate phase two implementation will occur at the Provider Data Management/Credential Verification Organization (PDM/CVO) go-live on July 31, 2023.
- CSR 2487 is scheduled to implement April 24, 2022. It will require the Fiscal agent to implement new denial and termination reason codes to be applied to provider taxonomies and Medicaid and NC Health Choice health plans when the Provider Operations License Limitations Review Committee renders a decision to limit, deny or terminate a provider's participation due to license limitations imposed by the licensing boards as provided in CFR 455.412. This CSR will put measures in place to prevent providers with license limitations from re-enrolling without first being reviewed and approved by the Committee.

NC Session Law 2021-62 repealed portions of the 2020 COVID-19 Recovery Act, requiring the resumption of provider fingerprint-based criminal background checks beginning July 29, 2021. Notifications were sent in mid-November to all providers for whom fingerprinting was delayed. Those providers were given thirty calendar days to respond to the notification. Failure of a provider to respond by the deadline may result in termination from the Medicaid and NC Health Choice health plans.

Monitoring the Fiscal Agent's performance during provider enrollment record maintenance and termination has continued, as well as monitoring performance of vendors, contractors, and prepaid health plans (PHPs). Provider Operations ensures approved providers meet the qualification requirements and that ineligible providers are terminated in a timely manner when they fail to meet the Medicaid and NC Health Choice (NCHC) program standards. Provider Operations is also responsible for monitoring the Fiscal Agent's performance during the provider enrollment application process to ensure approved providers meet qualification requirements and documentation is maintained to effectively evaluate the approved enrollment of Medicaid and NC Health Choice Providers. During this quarter, Provider Operations monitored 19 licensure boards and 3 state agency boards, reviewing approximately 110 board sanctions associated with providers, and approximately 81 provider applications.

The Department's NC Area Health Education Centers (AHEC) partner made over 2,100 contacts to providers through their regional coaches' provider engagement and education activities. Encounters took place through virtual, telephone, e-mail, or on-site engagement, with a focus on advance medical home providers, community health workers, and providers interested in Tailored Care Management education. There were 671 encounters reported in September, 706 in October, and 743 in November, representing a 56% increase in the number of encounters from last quarter.

The Medicaid Provider Ombudsman has received 458 cases directly through the Provider Ombudsman Listserv this quarter. The team responded directly to 105 inquiries and worked to assign other cases to the appropriate business owner, including the Prepaid Health Plans, General Dynamics Information Technology/NCTracks, or another operational unit within the Department. The Provider Ombudsman reengages with the business owner if a case has aged 7-days or greater, providing continued outreach and support for an additional 93 cases over the last three months. Open cases are also monitored bi-weekly through closure.

The Provider Relations team successfully processed over 650 mass changes, 326 Carolina ACCESS applications, 22 CCNC Network Affiliation requests, and two Eastern Band of Cherokee Indians-Tribal Option enrollment requests.

The above-mentioned activities also run alongside staff involvement in provider communication and engagement activities, the development of new Division initiatives, and continued partnering and vendor management activities.