

WRITTEN SECTION REPORTS

CLINICAL POLICY AND PROGRAMS REPORT

REPORT PERIOD DECEMBER 2, 2019 THROUGH FEBRUARY 28, 2020

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

The N.C. Physician Advisory Group met on 12/12/2019, 01/23/2020, 02/27/2020

The Pharmacy & Therapeutic Committee met on 1/14/2020, 02/11/2020

Recommended Pharmacy

Prior Approval Criteria Antiemetic Agents- 12/12/2019
Prior Approval Criteria Cystic Fibrosis Agents-12/12/2019
Prior Approval Criteria Monoclonal Antibodies-12/12/2019
Prior Approval Criteria Movement Disorders-12/12/2019
Prior Approval Criteria Neuromuscular Blockers-12/12/2019
Prior Approval Criteria PCSK9 Inhibitors-12/12/2019
Prior Approval Criteria Relistor-12/12/2019
Prior Approval Criteria Triptans-12/12/2019
Prior Approval Criteria Hepatitis C-01/23/2020
Prior Approval Criteria Acthar Gel-01/23/2020
Prior Approval Criteria Antinarcology Agents-01/23/2020
Prior Approval Criteria Systemic Immunomodulators-01/23/2020
Prior Approval Criteria Opioid Analgesics-01/23/2020
Prior Approval Criteria Exondys and Vyondys-01/23/2020
Prior Approval Criteria Gattex-01/23/2020
Prior Approval Criteria Growth Hormones-01/23/2020
Prior Approval Criteria Juxtapid and Kynamro-01/23/2020
Prior Approval Criteria Abilify Mycite-02/27/2020
Prior Approval Criteria Arikayce-02/27/2020
Prior Approval Criteria Endari-02/27/2020
Prior Approval Criteria Gocovri/Osmolex/Inbrija-02/27/2020
Prior Approval Criteria Pulmozyme-02/27/2020
Prior Approval Criteria Xifaxan-02/27/2020

2. Policies Posted for Public Comment

- 1A-34, End Stage Renal Disease (ESRD) Services 12/04/2019 - 1/18/2020
- 1S-7 Gene Expression Profiling for Breast Cancer 1/22/2020 - 03/07/2020
- Prior Approval Criteria Antiemetic Agents 1/27/2020 - 3/12/2020
- Prior Approval Criteria Relistor 1/27/2020 - 3/12/2020
- Prior Approval Criteria Cystic Fibrosis 11/26/2019- 1/10/2020
- Prior Approval Criteria Monoclonal Antibodies 1/27/2020 - 3/12/2020
- Prior Approval Criteria Treatment for Movement Disorders 1/27/2020 - 3/12/2020
 - Prior Approval Criteria Neuromuscular Blocking Agents - Trikafta 1/27/2020 - 3/12/2020
 - Prior Approval Criteria PCSK9 Inhibitors 1/27/2020 - 3/12/2020
 - Prior Approval Criteria Outpatient Pharmacy - Triptans 1/27/2020 - 3/12/2020

3. New or Amended Policies Posted to Medicaid Website

- 8A, Enhanced Mental Health and Substance Abuse Services 12/15/19
- 8A-1, Assertive Community Treatment (ACT) Program 12/15/19
- 8A-2, Facility-Based Crisis Management for Children and Adolescents 12/15/19
- 8A-6, Community Support Team (CST) 12/15/19
- 8B, Inpatient Behavioral Health Services 12/15/19
- 8C, Outpatient Behavioral Health Services Provided by Direct-Enrolled Providers 12/15/19

- 8D-1, Psychiatric Residential Treatment Facilities for Children under the Age of 21 12/15/19
- 8D-2, Residential Treatment Services 12/15/19
- 8E, Intermediate Care Facilities for Individuals with Intellectual Disabilities 12/15/19
- 8F, Research-Based Behavioral Health Treatment (RB-BHT) For Autism Spectrum Disorder (ASD) 12/15/19
- 8I, Psychological Services in Health Departments and School-Based Health Centers Sponsored by Health Departments to the under-21 Population 12/15/19
- 8J, Children's Developmental Service Agencies (CDSAs) 12/15/19
- 8L, Mental Health/Substance Abuse Targeted Case Management 12/15/19
- 8-O, Services for Individuals with Intellectual and Developmental Disabilities and Mental Health or Substance Abuse Co-Occurring Disorders 12/15/19
- 8-P, North Carolina Innovations 12/15/19
- 10B, Independent Practitioners (IP) 01/15/2020
- 10C, Outpatient Specialized Therapies - Local Education Agencies (LEAs) 01/15/2020
- Prior Approval Criteria Migraine Therapy Calcitonin Gene Related Inhibitors- 12/04/2019
- Prior Approval Criteria Emflaza-12/06/2019
- Prior Approval Criteria Systemic Immunomodulators-12/09/2019
- Behavioral Health Clinical Edits Criteria Pediatrics-12/16/2019
- Behavioral Health Clinical Edits Criteria Adults-12/16/2019
- Prior Approval Criteria Monoclonal Antibodies-01/29/2020

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

June 1 – Aug 31, 2019 update left out of previous report:

- Clinical Coverage policy 5A-3, Nursing Equipment & Supplies was posted for public comment 06/28 – 08/12/2019. NCTracks System work is currently being completed, and the updated policy is expected to be posted to the NC Medicaid website on 10/01/2019.

Sept 1 – Nov 30, 2019 update left out of previous report:

- As planned, an updated version of clinical coverage policy 5A-3, Nursing Equipment & Supplies was posted to the NC Medicaid website 10/01/2019. Updates included adding coverage for HCPCS code A7048 (vacuum drainage collection unit and tubing kit); clarifying medical necessity criteria for utilization of sterile and non-sterile gloves; expanding the universe of acceptable prior authorization (PA) documentation for replacing lost/stolen/damaged medical equipment and supplies during natural disasters; streamlining the process for replacing non-functional external insulin infusion pumps; simplifying the process for requesting overrides of quantity or lifetime expectancy limits; adding monthly quantity limits for sterile and non-sterile gloves.

Dec 2 – Feb 28, 2020:

- The DMEPOS program and provider reimbursement department are preparing for the 2019 upper payment limit demonstration required by CMS annually on select DME items in compliance with the Consolidated Appropriations/21st Century Cures Act.

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

June 1 – Aug 31, 2019 update left out of previous report:

- An update to policy 10B, Outpatient Specialized Therapies, Independent Practitioners was posted to the NC Medicaid website on 06/01/2019. This policy amendment included changes to align with language in policy 10C, Outpatient Specialized Therapies, Local Education Agencies (LEAs) which were made in response to the 01/25/2019 CMS approval of SPA #18-0005. Other changes included: removal of the prior authorization documentation requirement for independent practitioner program therapists to include the frequency at which the beneficiary receives the same type of therapy in school; the requirement that a therapy evaluation be performed within 6 months of the requested start date of a prior authorization, was updated to within 3 months of the requested start date of a prior authorization; and added billing guidance for therapy co-treatments.

Dec 2 – Feb 28, 2020:

- No policy updates this period.

6. Long-Term Services and Supports (LTSS)

Comprehensive Independent Assessment Entity (CIAE)

On Jan. 31, 2020, the North Carolina Department of Health and Human Services announced that Keystone Peer Review Organization, Inc. (KEPRO), received the contract as the Comprehensive Independent Assessment Entity (CIAE). KEPRO was selected based on a thorough and fair evaluation of responses submitted to the Request for Proposal released by the Department in March 2019.

The CIAE will streamline access to Medicaid Long-Term Services and Supports (LTSS), providing beneficiaries a much-needed single point of entry for accessing Medicaid LTSS services and streamlining the process between initial contact and service enrollment. The CIAE will conduct assessments and screenings to determine eligibility for the following LTSS programs:

- State Plan Personal Care Services (PCS)
- Community Alternatives Program for Children (CAP/C)
- Community Alternatives Program for Disabled Adults (CAP/DA)

In addition, the CIAE will also provide management and oversight for the Pre-Admission Screening and Resident/Review process (PASRR) Level II and serve as North Carolina's local contact agency (LCA) for nursing home residents who have requested information about options for less restrictive care settings.

The Department began onboarding the KEPRO vendor with a contract kick-off meeting on February 5, 2020 and continues training in preparation for the full program implementation. Implementation of the initiative will be approached in phases with assessments for PCS beginning in April and all services conducted by KEPRO by June 30, 2020.

Dual Eligible Special Needs Plans: CY 2021 Medicare-Medicaid Integration and Unified Appeals and Grievance Requirements for Dual Eligible Special Needs Plans (D-SNPs)

In April 2019, the Centers for Medicare and Medicaid Services (CMS) finalized rules to implement the new statutory provisions brought forth by the Bipartisan Budget Act (BBA) of 2018. The BBA of 2018 permanently authorized Dual Eligible Special Needs Plans (D-SNPs), strengthened Medicare-Medicaid integration requirements, and directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for D-SNPs.

The April 2019 Final Rule requires that starting in Calendar Year (CY) 2021, D-SNPs must meet the new Medicare-Medicaid integration criteria in at least one of the following ways:

- Meeting the requirements to be designated as a fully integrated Dual Eligible SNP (FIDE SNP), as defined in 42 CFR 422.2;
- Meeting the requirement to be designated as a Highly integrated D-SNP (HIDE SNP), as defined in 42CFR 422.2; or
- Having a contract with the state which specifies a process to share information/notify the state of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk individual enrolled in the D-SNP, as defined in 42 CFR 422.107 (d).

Under any integration method, D-SNPs are to:

- Coordinate the delivery of Medicare and Medicaid services;
- May provide coverage of Medicaid services, including long-term services and supports and behavioral health services;
- Have a contract with the state Medicaid agency; and
- Adhere to the April 2019 Final Rule established standards to assist members in:
 - o Obtaining Medicaid-covered services and resolving coverage & authorization issues, and;
 - o Providing assistance with filing grievances and requesting appeals.

Additionally, the April 2019 Final Rule requires the establishment/streamlining of a Unified Medicare and Medicaid Appeals and Grievance Process, starting in CY 2021. Currently Medicare and Medicaid processes differ in a variety of ways that can be confusing and harmful for enrollees while also leading to duplicative activities. The unified processes are to be developed in a manner which:

- Adopts a most enrollee-protective Medicare-Medicaid rule;
- Is compatible with unified timeframes and consolidated access to external review;
- Accounts for differences under state Medicaid plans; and
- Is easily navigable by enrollees.

Key elements of the Unified Appeals and Grievance Processes include:

- The adoption of a single plan-level grievance process with uniform timelines and procedures (§422.630), and integration of coverage determination (§ 422.631) and plan level appeals (integrated considerations § 422.633), through which the plan should apply Medicare and Medicaid coverage criteria, have one set of timelines and rules for parties and representation;
- The requirement of a single written notification of all applicable grievances and appeal rights;
- The implementation of one single integrated denial notice (§ 422.631(d) (1)), which focuses on the use of plain language to help enrollees “easily determine the status of the grievance or appeal”;
- The continuation of benefits while the appeal is pending (§ 422.632); and
- The assurance that subsequent appeals levels remain unchanged, as exemplified by the Medicaid’s state fair hearing and any other state external review and Medicare’s Appeals Council.

All D-SNPs are required to have executed contracts with applicable state Medicaid agencies – State Medicaid Agency Contract (SMAC), as provided under section 1859(f)(3)(D) of the SSA and 42 CFR 422.107. These executed contracts must be submitted to CMS by the first Monday in July for the upcoming contract year (i.e. CY 2021 contracts must be submitted to CMS by July 6, 2020)

Staff from across the Division are working to determine the most feasible methods to meet the integration requirements, unify grievance and appeals procedures as appropriate, in addition to drafting and implementing needed contractual and operational modifications, in preparation for the 2019 Final Rule implementation beginning CY 2021.

Nursing Homes

Patient Driven Payment Model and the Optional State Assessment

Effective October 1, 2019, the Center for Medicare and Medicaid Services (CMS) replaced the current case-mix model for nursing home reimbursement, the Resource Utilization Groups Version IV (RUG-IV) with the Patient Driven Payment Model.

Currently, NC Medicaid uses the Resource Utilization Groups, Version III (RUG III) for nursing home reimbursement and will continue to use it to determine the nursing home case mix reimbursement rate until further notice. CMS has developed the Optional State Assessment (OSA) to assist those States which rely on the RUG-III and IV assessments as a basis for nursing home payment.

Effective 10/1/2020, in order to ensure sufficient data is available for the calculation of the nursing home case mix reimbursement rate, NC Medicaid will be requiring OSA submissions by Nursing Home Providers.

Adult Care Homes

General Assembly of North Carolina; Session 2019 Session Law 2019-240 Senate Bill 537 Part I. Establish New Adult Care Home Payment Methodology Section 1. (a)

It is the intent of the GA to provide funding to Adult Care Homes (ACH) in the State in a manner that recognizes the importance of a stable and reliable funding stream to ensure access, choice and quality of care within the adult care home segment of the care continuum. The General assembly has directed DHHS to establish and convene a workgroup to study

and evaluate reimbursement options for services provided by ACH that take into account all funding streams and develop a new service definition or definitions, under Medicaid Managed Care for these services.

DHHS, Medicaid established and convened the work group and the first stakeholder meeting was held on January 24, 2020. Plans for five stakeholder meetings consisting of industry leaders, persons living the experience, advocacy groups, families and caregivers. Partnering NC Divisions include: Aging and Adult Services, Health Service Regulation, Mental Health, Developmental Disabilities and Substance Abuse Services and Health Benefits. Representatives from the NC Health Care Facilities Association, NC Assisted Living Association, NC Senior Living Association and Disability Rights of NC and other stakeholders.

The work group will conduct research and leverage member knowledge in the development of a new service definition (s) and include the following: 1) Support of alternative payment models under state waivers, including pay-for-performance initiatives; 2) Best practices for long-term services and supports; and 3) Efficient payment methodologies.

DHHS will submit a report to the General Assembly no later than December 1, 2020 of the new service definition or definitions developed by the workgroup.

Home Health

Electronic Visit Verification (EVV)

Section 12006(a) of the 21st Century Cures Act mandates that states implement EVV for all Medicaid personal care services (PCS) and home health services (HHCS) that require an in-home visit by a provider. This applies to PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115; and HHCS provided under 1905(a)(7) of the Social Security Act or a waiver.

EVV is a method used to verify visit activity for services delivered as part of home- and community-based service programs. EVV offers a measure of accountability to help ensure that individuals who are authorized to receive services in fact receive them.

The Cures Act requires States implement EVV for PCS by January 1, 2020 and for Home Health Services by January 1, 2023. CMS allowed an extension for PCS to January 1, 2021 for States who requested a good-faith effort exemption. NC was granted a Good Faith Effort exemption to delay EVV implementation to January 1, 2021. Failure to comply by January 1, 2021 may result in incremental FMAP reductions.

North Carolina is currently drafting the Request for Proposal (RFP) to procure an EVV system that supports an Open Vendor Model of EVV. An Open Vendor Model allows providers to utilize the state procured system but to also use the EVV system of choice. An Open Vendor model is also capable of supporting both managed care and fee for service providers.

In addition to drafting the RFP, NC Medicaid has begun stakeholder engagement across all program areas. The posting of a utilization survey to gauge EVV use across the state, Regional Trainings to inform providers of the upcoming requirement, and Webinars directed towards the CAP Waiver Case Management Agencies are the beginning phases of engagement. As we move toward implementation, Medicaid will increase stakeholder engagement focusing on beneficiary engagement and increased training for both providers and beneficiaries once an EVV solution is procured.

7. Behavioral Health Clinical Policy Updates:

Community Support Team (CST)

The CST SPA was approved by CMS in October 2019 and the policy went live November 1, 2019.

Peer Support Specialist (PSS)

The PSS SPA was approved by CMS in October 2019 and the policy went live November 1, 2019.

NC Medicaid Clinical Coverage Policy Changes: Licensed Professional Counselors Act and the Substance Abuse Professional Practice Act

On November 6, 2019, the NC General Assembly approved Session Law 2019-240 Senate Bill 537. The session law amended board names, licensure and certification names for the Licensed Professional Counselors Act and the Substance Abuse Professional Practice Act which are included in clinical coverage policies. The following technical changes will be made to the relevant behavioral health policies:

- “Licensed Professional Counselors Act” will be changed to “Licensed Clinical Mental Health Counselors Act”;
- “Board of Licensed Professional Counselors” will be changed to “Board of Licensed Clinical Mental Health Counselors”;
- “Licensed Professional Counselor (LPC)” licensure name will be changed to “Licensed Clinical Mental Health Counselor (LCMHC)”;
- “Licensed Professional Counselor Associate (LPCA)” licensure name will be changed to “Licensed Clinical Mental Health Counselor Associate (LCMHCA)”;
- “Licensed Professional Counselor Supervisor (LPCS)” licensure name will be changed to “Licensed Clinical Mental Health Counselor Supervisor (LCMHCS)”;
- “NC Substance Abuse Professional Practice Board” will be changed to “NC Addictions Specialist Professional Practice Board”; and
- “Certified Substance Abuse Counselor (CSAC)” certification name will be changed to “Certified Alcohol and Drug Counselor (CADC)”.

PROVIDER SERVICES REPORT

Since our last report to the MCAC, our section has undergone a name change from Provider Services to Provider Operations.

Since the launch to Medicaid Managed Care was suspended, Provider Operations has focused on activities that strengthen vendor monitoring, compliance and oversight, data accuracy, and provider readiness. We have onboarded four provider engagement specialists to assist with provider outreach and support. Their activities include efforts to help providers with Medicaid enrollment record clean-up, to assist providers who have been suspended for incomplete reverifications, and to assist with the accuracy of taxonomy codes. This work will ensure the accuracy of the provider enrollment information and improve data transmissions between systems and the accuracy of the Enrollment Broker Provider Directory.

Provider Operations also continues its relationship with NC AHEC. In collaboration with Provider Operations and as part of our collective PHP monitoring activities, AHEC meets one on one with PHPs, taking questions, receiving feedback from the field, and supporting PHPs in their ongoing relationships with providers who have contracted with them. AHEC is also working with the DHB Care and Quality section building framework to support AMH providers; developing quality measures, training modules, and engaging in other readiness activities.

We recently completed reviews and revisions of all our business procedures. Over time, our team has built a repository of procedures to outline each of our business functions.

We initiated the addition of a few taxonomy codes to the NCTracks provider New Taxonomy Code information. Slated for deployment on April 26, 2020, the following new provider taxonomy codes will be available during the application process for Allopathic and Osteopathic Physicians:

- Level 2 Taxonomy: 208M00000X - Hospitalist
- Level 3 Taxonomy: 207RA0001X - Advanced Heart Failure & Transplant Cardiology
- Level 3 Taxonomy: 207SG0201X - Clinical Genetics (M.D.)
- Level 3 Taxonomy: 208VP0014X - Interventional Pain Medicine
- Level 3 Taxonomy: 207LP2900X - Anesthesia Pain Medicine

Members of our staff have been selected to join the Accountable Care Organization (ACO) workgroup. Details around this can be found in a Policy Paper titled, North Carolina's Medicaid Accountable Care Organizations (ACOs) for Standard Plans and Providers: Building on the Advanced Medical Home Program to Drive Value-Based Payment, located here: https://files.nc.gov/ncdhhs/ACO_White_Paper_Final_20200108.pdf. The work of this group can continue despite the suspension as there is much to be accomplished ahead of any plans to lift the suspension and move forward with managed care.

Members of our staff have also been selected to serve on the Evaluation Committee for the Health Opportunities Pilot (including the Lead Pilot Entity RFP). This workgroup is expected to begin meeting once or twice a week for an average of 4 hours per meeting through the month of May.

We also have staff serving on Governance Committees, engaged in efforts to support a PDM/CVO provider enrollment model, collaborating with multiple workgroups across the Divisions to analyze provider data and resolve discrepancies. These are special efforts in addition to the daily operational tasks of provider monitoring, support, and issue resolution, stakeholder engagement, and provider communication.

Provider Operations recently wrapped up the Single State Audit and kicked off the performance audit.

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