

## **WRITTEN SECTION REPORTS**

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# CLINICAL POLICY AND PROGRAMS REPORT

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REPORT PERIOD JUNE 1, 2019 THROUGH AUGUST 31, 2019

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

The N.C. Physician Advisory Group met on 6/27/19, 7/25/19, and 8/22/19

The Pharmacy & Therapeutic Committee met on 6/11/19, 7/9/19, and 8/13/19

### **Recommended Pharmacy**

- Prior Approval Criteria Cialis (Tadalafil) - 6/27/29
- Prior Approval Criteria Epinephrine Auto-Injections (Symgepi) - 6/27/29
- Prior Approval Criteria Hepatitis C Virus Medications (update) - 6/27/29
- Prior Approval Criteria Systemic Immunomodulators (Cimzia) - 6/27/29
- Prior Approval Criteria Gocovri & Osmolex (criteria Osmolex XR) - 6/27/29
- Prior Approval Criteria Opioid Analgesics (Tramadol ER, Apadaz, Conzip) - 6/27/29
- Prior Approval Criteria Hematinics (Retacrit and Mircera) – 7/25/19
- Prior Approval Criteria Cystic Fibrosis (Symdeko) – 7/25/19
- Prior Approval Criteria Opioid Dependence (generic buprenorphine/naloxone film) – 7/25/19
- Prior Approval Criteria Topical Local Anesthetics (Zilacaine & LidoPure patches) – 7/25/19
- Prior Approval Criteria Emflaza - 8/22/19
- Prior Approval Criteria Systemic Immunomodulators (Skyrizi and Stelara) - 8/22/19

### **Recommended Clinical Coverage Policies**

- 8G, Peer Support Services (PSS) - 6/27/29
- 1A-22, Medically Necessary Circumcision - 6/27/29
- 11A-1, HSCT for Acute Lymphoblastic Leukemia (ALL) - 6/27/29
- 11A-2, HSCT for Acute Myeloid Leukemia (AML) - 6/27/29
- 11A-3, HSCT for Chronic Myeloid Leukemia (CML) - 6/27/29
- 11A-5, Allogeneic Hematopoietic Transplant for Genetic Diseases & Acquired Anemias - 6/27/29
- 11A-6, HSCT in the Treatment of Germ Cell Tumors - 6/27/29
- 11A-7, HSCT for Hodgkin Lymphoma - 6/27/29
- 11A-8, HSCT for Multiple Myeloma, POEMS Syndrome, & Primary Amyloidosis - 6/27/29
- 11A-9, Allogeneic HSCT for Myelodysplastic Syndromes & Myeloproliferative Neoplasms - 6/27/29
- 11A-11, HSCT for Non-Hodgkin Lymphoma - 6/27/29
- 11A-14, Placental and Umbilical Blood as a Source of Stem Cells - 6/27/29
- 11A-16, HSCT for Chronic Lymphocytic Leukemia (CLL) & Small Lymphocytic Lymphoma (SLL) - 6/27/29
- 9 – Outpatient Pharmacy – 7/25/19
- 2A-3, Out-of-State Services - 8/22/19
- 1A-20, Sleep and Polysomnography Studies - 8/22/19
- 1A-5, Genetic Testing for Susceptibility to Breast & Ovarian Cancer (BRCA) - 8/22/19

### **PAG Notifications**

- None

## **2. Policies Posted for Public Comment**

- 1B, Physician's Drug Program (PDP) – 6/28/19
- 1B-1, Botulinum Toxin Treatment: Serotype A (Botox, Dysport & Xeomin) Serotype B (Myobloc) – 6/28/19
- 1B-2, Rituximab (Rituxan) - 6/28/19
- 1B-3, Intravenous Iron Therapy– 6/28/19
- 5A-3, Nursing Equipment & Supplies - 6/28/19
- 9C, Mental Health Drug Management Program - 6/10/19
- 3K-2, Community Alternatives Program for Disabled Adults (CAP/DA) -7/11/19
- Prior Approval Criteria Cialis (Tadalafil) – 7/16/19
- Prior Approval Criteria Epinephrine Auto-Injections (Symgepi) - 7/16/19
- Prior Approval Criteria Gocovri and Osmolex (criteria Osmolex XR) - 7/16/19
- Prior Approval Criteria Hepatitis C Virus Medications (update) - 7/16/19
- Prior Approval Criteria Opioid Analgesics (Tramadol ER, Apadaz, Conzip) - 7/16/19
- Prior Approval Criteria Systemic Immunomodulators (Cimzia) - 7/16/19
- 11A-1, HSCT for Acute Lymphoblastic Leukemia (ALL) - 7/16/19
- 11A-2, HSCT for Acute Myeloid Leukemia (AML) - 7/16/19
- 11A-3, HSCT for Chronic Myeloid Leukemia (CML) - 7/16/19
- 11A-5, Allogeneic HSCT for Genetic Diseases & Acquired Anemias - 7/16/19
- 11A-6, HSCT in the Treatment of Germ Cell Tumors - 7/16/19
- 11A-7, HSCT for Hodgkin Lymphoma - 7/16/19
- 11A-8, HSCT for Multiple Myeloma, POEMS Syndrome & Primary Amyloidosis - 7/16/19
- 11A-9, Allogeneic HSCT for Myelodysplastic Syndromes & Myeloproliferative Neoplasms - 7/16/19
- 11A-11, Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas - 7/16/19
- 11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells - 7/16/19
- 11A-16, HSCT for Chronic Lymphocytic Leukemia (CLL) & Small Lymphocytic Lymphoma (SLL) - 7/16/19
- 8G, Peer Support Services (PSS) - 7/16/19
- 3D, Hospice Services - 7/23/19
- Prior Approval Criteria Hematinics (Retacrit and Mircera) - 8/13/19
- Prior Approval Criteria Topical Local Anesthetics ((Zilacaine & LidoPure patches) - 8/13/19
- Prior Approval Criteria Opioid Dependence Therapy Agents (generic buprenorphine patch)- 8/13/19
- Prior Approval Criteria Cystic Fibrosis (Symdeko)- 8/13/19
- 3K-1, Community Alternatives Program for Children (CAP/C) - 8/16/19

## **3. New or Amended Policies Posted to Medicaid Website**

- 10B, Independent Practitioners (IP) – 6/01/19
- 10C, Outpatient Specialized Therapies - Local Education Agencies (LEAs) –6/15/19
- 8A, Enhanced Mental Health and Substance Abuse Services (Multisystemic Therapy) – 6/15/19
- 8A-6 Community Support Team – 7/1/19
- 9A, Over-The-Counter Products – 7/1/19
- 1C-1, Podiatry Services – 7/1/19
- 1A-39, Clinical Trial Services for Life Threatening Conditions –7/1/19
- 8A, Enhanced Mental Health and Substance Abuse Services (Diagnostic Assessment) – 8/1/19
- 8F, Research-Based Behavioral Health Treatment (RB-BHT) For Autism Spectrum Disorder - 8/15/19
- 1A-8, Hyperbaric Oxygenation Therapy - 8/15/19
- 1A-12, Breast Surgeries - 8/15/19
- 1N-2, Allergy Immunotherapy - 8/15/19
- 15, Ambulance Services – 8/15/19

### **New or Amended PA Criteria Posted**

- No report received

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

- No report received

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

- No report received

#### 6. Long-Term Services and Supports (LTSS)

##### **Hospice**

The CMS-mandated Hospice Payment Reform is nearly completed. The final Payment Reform activity was implemented within NC Tracks to reprocess claims with a date of service on or after January 1, 2016. NC Medicaid has validated the process, updated providers in the July 2019 bulletin, and claims are slated to be reprocessed with the October 8, 2019 check write.

The 3D-Hospice Clinical Coverage Policy has passed a final public comment period and will go into effect October 2019.

##### **Home Health**

CMS Final Rule [CMS-1689 -F] continues to be reviewed and may require system changes as CMS seeks to change the methodology of Home Health reimbursement with a focus toward more value-based rather than volume-based care, as well as allow for more Home Health innovation.

##### **Home Infusion Therapy**

The 3H-Home Infusion Therapy Clinical Coverage Policy is being reviewed and updated to comply with CMS-1689-F. CMS has expanded Home Infusion Therapy Services to cover “transitional home infusion drugs” as well as remote monitoring for these specific drugs. After stakeholder input, additional planned revisions aim to achieve the following:

1. Update formatting and grammar.
2. Remove - Monitoring of Amphotericin B due to a great decrease in utilization. CPT Code T1002 and SD modifier will be removed as covered therapy.
3. Clarified ambiguous policy language.
4. All references have been verified and updated as needed.
5. Reorganized attachments, incorporating B into A and removing Attachment C.
6. Remove forms from the policy for consistency.

##### **Private Duty Nursing**

DHB held a Private Duty Nursing (PDN) stakeholder meeting on June 27, 2019 to discuss quality improvement initiatives and provide program updates. The focus of the meeting was to share results of the PDN beneficiary/family and agency surveys that were distributed in May 2019 to gather input about any program concerns, ideas for process improvement, and to identify information that they would like to receive that is not currently being provided. DHB received 79 beneficiary/family and 32 PDN agency responses to the survey. All input is being considered as work is underway to revise PDN policies 3G-1, Private Duty Nursing for Beneficiaries Age 21 and Older and 3G-2, Private Duty Nursing for Beneficiaries Under 21 Years of Age, with a target date of the November/December combined 2019 Physician Advisory Group meeting on December 12, 2019.

## **7. Behavioral Health IDD Section**

### **Treatment for Autism Spectrum Disorder:**

The policy for Research Based Interventions for the Treatment of Autism Spectrum Disorder has been posted to our website.

### **TBI Waiver:**

Alliance continues to move individuals through the Level of Care and Individual Service Plan processes. Individuals are actively receiving TBI Waiver Services. Both the State and Alliance have TBI Waiver Stakeholder groups who have met and will continue to meet to learn from this model waiver.

### **Innovations Waiver:**

The NC Innovations Waiver renewal was approved by CMS with an effective date of 7/1/19.

### **Behavioral Health Clinical Policy Updates:**

#### **Services for Substance Use Disorders:**

The goal of the 1115 SUD demonstration waiver is to improve access to SUD services in North Carolina. North Carolina, along with most other states, selected the American Society of Addiction Medicine (ASAM) criteria as our best practice model. Four new services will be created (Clinically Managed Low Intensity Residential, Clinically Managed Population Specific High-Intensity Residential Services, Ambulatory Withdrawal Management with Extended On-Site Monitoring, and Clinically Managed Residential Withdrawal Management) and the other SUD services will be revised to be compliant with ASAM. Our application also included a waiver of the IMD exclusion for SUD services. We will be submitting revised State Plan Amendments, policies, and rules over the next several years. As of September 2019, we have drafted revisions for our State Plan Amendments and are formulating the rates for the related SUD policies in preparation for the future submission to CMS.

### **Community Support Team (CST)**

DHB has submitted a SPA to CMS for CST.

### **Peer Support Specialist (PSS)**

The Peer Support Services Policy was reviewed by the NC Physician Advisory Group in June 2019. The policy was posted on the NC Medicaid website on July 15, 2019 for 45-days to allow for public comment.

### **NC Medicaid Clinical Coverage Policy 8A – Enhanced Mental Health and Substance Abuse Services**

The Ambulatory Detoxification policy was updated on June 15, 2019 with an effective date of April 4, 2019. The service is no longer covered by NC Health Choice.

The Multisystemic Therapy policy was updated on June 15, 2019. The update removed the limit on billable units in a 24-hour period.

The Diagnostic Assessment policy was updated on August 1, 2019. The policy was updated to clarify one unmanaged diagnostic assessment is allowed per beneficiary per state fiscal year and to specify that the current edition of the American Society of Addiction Medicine (ASAM) should be utilized.

### **LME-MCO Contract Section Updates:**

#### **1915 (b) Waiver**

The 1915 (b) waiver renewal was approved by CMS with an effective date of 7/1/19.

### **External Quality Reviews (EQRs)**

Federal regulations require states to conduct external quality reviews of managed care organizations such as the LME-MCOs. These reviews are an analysis and evaluation by an external quality review organization (EQRO) of aggregated information on quality, timeliness, and access to the health care services that the managed care organization provides to Medicaid members. NC Medicaid contracts with the Carolinas Center for Medical Excellence (CCME), an EQRO, to conduct these reviews annual. Reviews have been completed for Alliance Behavioral Healthcare, Trillium, Eastpointe, Sandhills Center, Partners Behavioral Healthcare, Vaya Health and Cardinal Innovations. Review reports and the State summary report have been posted to the NC Medicaid website.

## PROVIDER SERVICES REPORT

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In February 2019, the North Carolina Department of Health and Human Services (NCDHHS ) announced the Prepaid Health Plans (PHPs) for Medicaid Managed Care when the program launches in February 1, 2020. Contracts were awarded to: AmeriHealth Caritas North Carolina, Inc., Blue Cross and Blue Shield of North Carolina, UnitedHealthcare of North Carolina, Inc., WellCare of North Carolina, Inc, and Carolina Complete Health. Health Plan info can be found here: <https://medicaid.ncdhhs.gov/health-plan-contact-information>

On June 6, 2019, Governor Cooper signed into law Session Law 2019-23 which revised portions of N.C.G.S. § 90-414.4. The legislation extends the deadline by which certain provider must connect to the Health Information Exchange Network, NC HealthConnex. Additionally, certain provider types are now exempt from the mandatory requirement to connect. Additional information can be found at: <https://files.nc.gov/ncdma/documents/files/Medicaid-Bulletin-2019-6.pdf>

In August 2019, as part of its effort to prepare providers for NC Medicaid Managed Care, NC Medicaid launched a time-limited, time-sensitive informational series, NC's Transition to Medicaid Managed Care: The Crossover Communication Series. Through this series, NC Medicaid provides guidance and resources to assist providers in ensuring beneficiary service continuity during the crossover period. Additional training courses are available in Skillport, the NCTracks Learning Management System. DHHS has also published an online Provider Playbook (found at: <https://medicaid.ncdhhs.gov/providers/provider-playbook-medicaid-managed-care>), where providers can access the latest information, tools and other resources to help them and their patients smoothly transition to Medicaid Managed Care. Additional resources will be added to the web page as they become available.

In September 2019, the Department announced the extension of open enrollment for Medicaid. Managed Care was scheduled to roll out in two phases, with part of the state beginning managed care services on Nov. 1, 2019, and most of the state beginning on Feb. 1, 2020. Managed Care will now go-live in one phase for the whole state beginning on Feb. 1, 2020. The timeline has been adjusted because DHHS cannot implement critical actions to go-live with managed care under the current continuing resolution budget.

Since the March 2019 NCDHHS presentation to MCAC on the enrollment broker, Maximus, a Special Bulletin has been released to update providers on the issues identified with the search function in the Enrollment Broker's Provider Directory. Maximus is required to maintain a beneficiary facing consolidated provider directory that works as a searchable repository of the most up-to-date information about NC Medicaid participating providers. DHHS is working with Maximus to resolve the issues. The long-term solution will support a fully searchable provider directory and is expected to be full- functioning by December 2019. More information about the enrollment broker can be found at: <https://www.ncdhhs.gov/news/press-releases/dhhs-awards-contract-medicaid-managed-care-enrollment-broker-services-maximus>

On September 6, 2019, DHHS announced the release of a Special Medicaid Bulletin, *NC Medicaid Temporary Flexibilities Due to Hurricane Dorian*. NCDHHS is permitted to implement a process to temporarily enroll providers on a time-limited expedited basis whenever the Centers for Medicare and Medicaid Services (CMS) issues approval to do so due to a natural disaster. Providers who are not enrolled in NC Medicaid, who have rendered services to NC Medicaid recipients during the state of emergency due to Hurricane Dorian can complete an application through the NCTracks Provider Portal.