WRITTEN SECTION REPORTS

(REPORT PERIOD JUNE 4, 2016 THROUGH SEPTEMBER 16, 2016)

1. POLICIES PRESENTED TO THE N.C. PHYSICIAN ADVISORY GROUP (PAG)

The N.C. Physician Advisory Group met on 07/28/16 and 08/25/16
The Pharmacy & Therapeutic Committee met on 07/12/16 and 08/09/16

Recommended Policies

- 1S-3, Laboratory Services - 07/28/16
- 8-P, North Carolina Innovations - 07/28/16
- 10-A, Outpatient Specialized Therapies - 08/25/16

Recommended Pharmacy

- PA Criteria Hepatitis C Virus Medications (add Epclusa)– 07/28/16
- PA Criteria Immunomodulators (add Taltz)– 07/28/16

2. POLICIES POSTED FOR PUBLIC COMMENT

- PA Criteria Entresto (sacubitril/valsartan) – 06/14/16
- PA Criteria Systemic Immunomodulators (add Xeljanz)– 06/14/16
- Annual Preferred Drug List (PDL) – 06/22/16
- PA Criteria Systemic Immunomodulators (add Taltz) – 08/04/16
- 8-P, North Carolina Innovations – 08/04/16
- 10-A, Outpatient Specialized Therapies – 08/31/16

3. POLICIES POSTED FOR ADDITIONAL PUBLIC COMMENT

- 5A, Durable Medical Equipment (Oxygen)– 08/05/16
- Annual Preferred Drug List (PDL) – 08/09/16 (This was a 45-day additional comment period)

4. AMENDED OR NEW POLICIES POSTED TO DMA WEBSITE

- 1S-4, Genetic Testing – 06/15/16
- 3-D, Hospice Services – 06/15/16
- 10-A, Outpatient Specialized Therapies – 06/15/16
- 1-F, Chiropractic Services – 07/01/16
- 1M-2, Childbirth Education – 07/01/16
- 3-L, State Plan Personal Care Services (PCS) – 07/01/16

1. BEHAVIORAL HEALTH CLINICAL POLICY UPDATES:

DMA continues to work with DMHDDSAS on improving Clinical Coverage Policy 8A, Mobile Crisis Management (MCM). Meetings with each LME-MCO and their MCM providers are in process to assess the current landscape of MCM services and guide the discussion on improvements that can be made to the policy to further enhance our state's crisis continuum. These listening sessions are scheduled to be completed by the end of October 2016.

DMA continues to work with DMHDDSAS on developing a new State Plan service for housing related activities, tentatively named Tenancy Support Services. Community stakeholder workgroups have been held and the Medicaid draft policy is in the process of being finalized.

Certified Community Based Health Clinic:

CCBHC grant proposal is due to SAMHSA by October 31, 2016. The pool of applicants has been narrowed down to two urban sites, Freedom House in Chapel Hill and Cone Behavioral Health in Greensboro; and three rural sites, Daymark in North Wilkesboro, Monarch in Albemarle, and Freedom House in Warrenton. One rural and one urban site will be chosen from this pool. Site visits are scheduled to commence the end of September and conclude the first week in October.

BEHAVIORAL HEALTH IDD SECTION UPDATES:

Treatment for Autism Spectrum Disorder:

DMA has begun stakeholder workgroups to develop a State Plan Amendment for Research Based Treatment of Autism Spectrum Disorder. The first meeting was held on 8/30/16 and two additional meetings are scheduled in September. This will be followed by two open forums, one in Raleigh and one in Winston-Salem, to obtain a wider stakeholder feedback.

TBI Waiver:

DMA is in the process of responding to a formal request for additional information from CMS on the TBI waiver.

Innovations Waiver:

The changes made in the Technical Amendment to the NC Innovations waiver are scheduled to be implemented November 1, 2016. DMA and DMH will be conducting readiness reviews of PIHPs beginning in September.

Clinical Coverage Policy 8P NC Innovations Waiver:

Clinical Coverage Policy 8P NC Innovations Waiver is currently posted for public comment until September 18, 2016. The policy has been updated to include the changes made in the Technical Amendment effective 11/1/16.

Home and Community Based Services Rule:

DMA has been working with CMS to develop the final version of the HCBS transition. DMA is submitting changes to the plan per the request of CMS. Once approved, the plan will be posted for public comment. The 'My Individual Experience Survey' has been developed to assess individuals' experiences with waiver service. For more information, please see the HCBS website at: https://www2.ncdhhs.gov/hcbs/myexperience.html.

LME-MCO Contract Section Updates:

CMS has published an updated version of 42 CFR 438, the managed care rule. This is the first major update since 2002, and has wide ranging changes including quality strategy, medical loss ratio, program integrity, and encounter data. Changes will be implemented over the coming months, and DHHS will monitor and update

2. Outpatient Pharmacy

Payment of Medicare Crossover Pharmacy Claims for QMB Recipients

Reimbursement of Medicare primary pharmacy claims for recipients with the Medicaid eligibility classification of "Q" have changed. Effective August 1, 2016, NCTracks pays QMB and QMB+ (a.k.a. Q class) Medicare crossover pharmacy claims according to state policy:

- Services covered by Medicaid are paid at Lesser of Logic.
- Services that are non-covered by Medicaid pay the full cost-share.

The determining factor regarding how the pharmacy crossover claims are reimbursed is whether or not the NDC is covered by Medicaid on the date of service. If the National Drug Code (NDC) is covered by Medicaid on the date of service, the claim will process to pay according to the Lesser of Logic pricing methodology. If the NDC is not covered by Medicaid on the date of service, it will process to pay 100 percent of Medicare cost share.

Note: For recipients who are MQBQ, Medicaid payment can only be made for services that have been approved/allowed by Medicare. There is no coverage for straight Medicaid claims for MQBQ recipients.

Medicare crossover pharmacy claims paid between March 2, 2015, and July 31, 2016, will be reprocessed to apply the state policy. A further announcement will be published once the date for reprocessing has been finalized.

For more information on the state policy regarding reimbursement of Medicare crossover claims for QMB recipients, including an explanation of Lesser of Logic, see the September 2015 Medicaid Bulletin.

Edit for Emergency Hemodialysis

New restrictions were implemented into NCTracks effective February 1, 2016 to limit services for certain undocumented aliens to dialysis services only. Providers will see RESTRICTIVE COVERAGE, EMERGENCY HEMODIALYSIS SERVICES ONLY when inquiring about eligibility information.

Federal law restricts coverage of services for undocumented aliens to those services that have been determined to treat an emergency condition as defined in 42 CFR 440.255. Previously, providers may have been reimbursed for non-emergency services provided on the same day for which eligibility was determined due to the need for hemodialysis. Now, a new edit will be applied to Medicaid claims for services provided that do not fit the criteria for hemodialysis. The EOB 00246 - SERVICE NOT ALLOWED FOR UNDOCUMENTED ALIENS will post to denied claims.

All Medicaid claims adjudicated after February 1, 2016 are subject to the new edit, regardless of dates of service. No claims reprocessing is scheduled to occur.

Eligibility does not guarantee claims payment. Claims for dialysis are still subject to Medicaid dialysis policy, which can be found on the Division of Medical Assistance (DMA) website at http://dma.ncdhhs.gov/providers/programs-services/medical/end-stage-renal-disease.

This new edit only applies to beneficiaries authorized because they need dialysis. Claims for services that are provided to undocumented aliens that are deemed eligible due to conditions unrelated to dialysis will not be impacted by this edit.

Preferred Drug List (PDL) Update

On June 28, 2016, under a priority review, the Food and Drug Administration (FDA) approved the first pan-genotypic oral direct-acting antiviral agent to treat chronic HCV infection, targeting genotypes 1-6. Epclusa, is a once daily fixed-dose combination of 400 mg sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and 100 mg velpatasvir, an HCV NS5A inhibitor. Epclusa is indicated alone for use in adults with HCV, without cirrhosis or with compensated cirrhosis; it is also indicated in combination with weight-based ribavirin in those with decompensated cirrhosis (Child-Pugh B or C). The recommended dose of Epclusa is one 400/100 mg tablet once daily, taken without regard to food, for 12 weeks.

Effective July 11, 2016, Epclusa will be preferred for HCV genotype 3 infections and Daklinza will move to non-preferred status on the NC Medicaid Preferred Drug List (PDL). The HCV DAA PDL Drug Class is pending review later this month. Any additional updates that may be made based on this review will be communicated in a future pharmacy newsletter article.

ANTIVIRALS (Continued)	
Hepatitis C Agents	
Preferred	**Non-Preferred**
Clinical criteria apply (HCV DAA Drug Class is Pending Review)	
Epclusa® Tablet (for genotype 2 and 3)	Daklinza® Tablet (for genotype 3) **(must request Sovaldi® in addition to Daklinza® with a separate PA)**
Technivie® Dose Pack (for genotype 4)	Epclusa® Tablet (for genotype 1, 4, 5 and 6)
Viekira® Pak (for genotype 1)	Harvoni® Tablet
	Olysio® Capsule
	Sovaldi® Tablet
	Zepatier® Tablet

Exemption from Pharmacy Co-pay

DMA has seen an increase in questions regarding Medicaid beneficiaries who are exempt from paying pharmacy co-pays. A Medicaid beneficiary is exempt from a co-payment for any one of the following:

a. The beneficiary is under 21 years of age.
b. The beneficiary resides in a nursing home facility, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) or a mental health hospital.
c. Adult care homes and hospice beneficiaries are responsible for co-payment.
d. The drug is classified as family planning (birth control medication). Exemption from the co-pay for family planning drugs is indicated on the drug file and does not require any additional indicators. Do not collect a co-pay for oral contraceptives.

e. The beneficiary is classified as a CAP beneficiary as indicated on the beneficiary's Medicaid Identification Card (MID card).
f. The beneficiary is pregnant. The co-payment exemption is made automatically by the claims processing system for an eligible beneficiary. In the event that the system does not override the copay, the pharmacy may use any of the ICD-10-CM codes listed below to indicate pregnancy. A "4" in the Prior Authorization Type Code or a "2" in the pregnancy indicator field on a point-of-sale (POS) claim also indicates an exemption from the co-payment deduction for pregnancy

ICD-10-CM Codes to Indicate Pregnancy

ICD-10-CM					
O09.00	O09.293	O09.521	O09.72	O09.90	Z34.02
O09.01	O09.299	O09.522	O09.73	O09.91	Z34.03
O09.02	O09.30	O09.523	O09.811	O09.92	Z34.80
O09.03	O09.31	O09.529	O09.812	O09.93	Z34.81
O09.10	O09.32	O09.611	O09.813	O36.80x0	Z34.82
O09.11	O09.33	O09.612	O09.819	O36.80x1	Z34.83
O09.12	O09.40	O09.613	O09.821	O36.80x2	Z34.90
O09.13	O09.41	O09.619	O09.822	O36.80x3	Z34.91
O09.211	O09.42	O09.621	O09.823	O36.80x4	Z34.92
O09.212	O09.43	O09.622	O09.829	O36.80x5	Z34.93
O09.213	O09.511	O09.623	O09.891	O36.80x9	
O09.219	O09.512	O09.629	O09.892	Z33.1	
O09.291	O09.513	O09.70	O09.893	Z34.00	
O09.292	O09.519	O09.71	O09.899	Z34.01	

National Average Drug Acquisition Cost (NADAC) Information

The NADAC pricing methodology was implemented into NCTracks on August 1, 2016. The state will use an average acquisition cost (AAC) reimbursement methodology to reimburse brand and generic drug ingredient costs. The National Average Drug Acquisition Cost (NADAC) will be used to determine the AAC when NADAC is available. If NADAC pricing is not available, the state will calculate the AAC as the Wholesale Acquisition Cost (WAC) + 0%. Reimbursement methodology will continue to include the lesser of NADAC, or WAC in absence of NADAC, the State Maximum Allowable Cost (SMAC) rate on file and the usual and customary (U&C) price submitted. The state will pay pharmacies a tiered dispensing fee as follows:

- $13.00 when 85% or more claims per quarter are for generic or preferred brand drugs with non-preferred generic alternatives,
- $7.88 when less than 85% of claims per quarter are for generic or preferred brand drugs and
- $3.98 for non-preferred brand drugs

Myers and Stauffer LC, the contractor for the Retail Price Survey, will operate the NADAC help desk. The operating hours for the help desk are Monday through Friday from 8 AM to 8 PM EST and contact information is included below.

Toll-free phone: (855) 457-5264
Electronic mail: survey@mslcrps.com
Facsimile: (317) 816-4134

Pharmacies are able to contact the help desk for any questions related to the NADAC survey process or if they have questions or concerns with a specific NADAC rate, such as those related to recent large price increases or drug shortages.

NADAC Weekly Files and NADAC Week to Week Comparison files can be found on the CMS Medicaid website at the link below:

https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html

NADAC Methodology (Part II) and NADAC Help Desk contact information:
https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html

The links regarding NADAC are also posted on the DMA Pharmacy website (http://dma.ncdhhs.gov/providers/programs-services/Prescription-drugs/Outpatient-Pharmacy-Services) under the Reimbursement Section.

Generic Dispensing Rate (GDR) Reports

DMA is working with CSRA to develop a report at the claim level detail that pharmacy providers can use to identify missed opportunities to maximize their GDR. A pharmacy will be able to obtain these analysis reports on an ad hoc basis. Further information will be provided when the reports are operational.

As a reminder, generic products, preferred brand products with non- preferred generics, compounded claims, and Roche diabetic supplies count as generics towards a pharmacy's GDR percentage.

Prescriptions for Preferred Brands with Non-preferred Generic Alternatives

Brand preferred/generic non-preferred prescriptions will reimburse at the NADAC brand cost basis when submitted using a DAW code of 1 or 8 (or 7 for NTI drugs). The use of DAW code 9 for brand preferred/generic non-preferred prescriptions will not allow these prescriptions to be correctly reimbursed and will result in an underpayment.

DMA is aware of concerns over the use of DAW codes 1 and 8 for brand preferred/generic non-preferred prescriptions and has identified a solution that will not require brand preferred/generic non-preferred prescriptions to be submitted with a DAW code in order for these prescriptions to be correctly reimbursed. This solution is currently being developed and tested by CSRA, the vendor responsible for maintaining NCTracks, and has been given a priority status. Further information will be provided once the solution is scheduled for implementation into NCTracks.

Until the final solution is implemented into NCTracks, pharmacy providers may submit their claims for brand preferred/generic non-preferred prescriptions using a DAW code 1 or 8 (or 7 for NTI drugs) as stated above. Pharmacy providers may also wait until the final solution is implemented into NCTracks when the use of a DAW code will not be required and resubmit their claims where underpayment has occurred at that time.

Coverage of Ulesfia Lotion Terminated

All Ulesfia products have been HCFA termed as of August 31, 2016 and/or no longer have Federal rebates agreements. As a result, Ulesfia Lotion will no longer be covered by NC Medicaid.

Procedures for Prior Authorization of Synagis for Respiratory Syncytial Virus (RSV) Season 2016/2017

The clinical criteria utilized by N.C. Medicaid (Medicaid) for the 2016/2017 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 increase risk of hospitalization for Respiratory Syncytial Virus (RSV) infection is available on line by subscription. The coverage season is November 1, 2016 through March 31, 2017. 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 diagnosis:
  - 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 required greater than 21% oxygen for at least 28 days after birth)
  - Hemodynamically significant acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures and; moderate to severe pulmonary hypertension
  - Infants with cyanotic heart disease may receive prophylaxis with cardiologist recommendation.
- Infants during first year of life with diagnosis:
  - Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways
- Infants less than 24 months of age with diagnosis:
  - Profound immune-compromise during RSV season
  - CLD of prematurity (see above definition) and continue to require medical support (supplemental oxygen, chronic corticosteroid or diuretic therapy) during 6 month period before start of second RSV season
  - Cardiac transplantation during RSV season

Prior Approval (PA) Request

Submit all PA requests for coverage of Synagis during the coverage season electronically at www.documentforsafety.org. The web-based program will process PA information in accordance with the guidelines for use. A PA request can automatically approve 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 immune-compromise 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 and 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 laboratory confirmed 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 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 should 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.

Synagis claims processing will begin on October 26, 2016 to allow sufficient time for pharmacies to provide Synagis by November 1, 2016. Payment of Synagis claims with date of service before October 26, 2016 and after March 31, 2017 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 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 DMA. Maintain Synagis dose authorizations in accordance with required record keeping time frames.

Provider Information

Providers without internet access should contact the 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. The form is available on DMA's website at http://dma.ncdhhs.gov/. Information about EPSDT coverage is on DMA's website http://dma.ncdhhs.gov/.

Technical Support

Technical support is available Monday to Friday from 8am to 5pm 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.

Upcoming Preferred Drug List Review Panel Meeting - September 29, 2016

The Medicaid and Health Choice Preferred Drug List (PDL) Review Panel was established by DHHS to conduct open meetings to review recommended policies and procedures related to the PDL and to address the public comments received during the PDL comment period. The administration and review of the North Carolina Medicaid and Health Choice PDL follows the Preferred Drug List Review Panel Guidelines and Procedures.

The next PDL panel meeting is scheduled for September 29, 2016, from 1–5 pm. The meeting will be held at the State Library Building at 109 E. Jones Street, Raleigh.

To sign up to speak at the PDL Review Meeting, send an email to: DMA.PDLReviewMeeting@lists.ncmail.net by 5 p.m. on Sept. 27, 2016. Include the name of the speaker, the represented organization and the drug name. You may attach any clinical information about the drug you wish the PDL Panel to review beforehand. Presentations are allowed only in the drug classes with changes and should not exceed three minutes.

3. PRACTITIONER, CLINICAL AND FACILITY SERVICES

Urine Drug Testing

DMA transitioned from CPT to HCPCS code for urine drug testing to align with Medicare reimbursement. 64 CPT codes for presumptive and definitive drug testing were end-dated June 30, 2016 and 7 new HCPCS codes were added effective January 1, 2016. Service limitations have been applied to the new codes and are as follows:

- Presumptive testing limited to twenty (20) tests per state fiscal year per beneficiary
- Requirement for a presumptive test to be done prior to definitive testing unless a presumptive screen is not commercially available for a specific substance.
- Only results producing a positive or unanticipated result on the presumptive screen are to be sent for confirmation

PROVIDER RECREDENTIALING

The Centers for Medicare and Medicaid Services requires that all Medicaid providers are revalidated (recredentialed) at least every five years. This is to ensure that provider enrollment information is accurate and current. The provider's credentials and qualifications will be evaluated to ensure that they meet professional requirements and are in good standing. The recredentialing process also includes a criminal background check on all owners and managing relationships associated with the provider record.

Every active NCTracks Provider must be recredentialed. It is crucial that all providers who receive a recredentialing notice promptly respond and begin the recredentialing process. Providers will receive a recredentialing letter 45 days before their recredentialing due date. If the provider does not complete the recredentialing process within the allotted 45 days, payment will be suspended until the recredentialing process is completed. The provider will also receive a termination notice. If the provider does not complete the recredentialing process within thirty (30) days from payment suspension and termination notice, participation in the N.C. Medicaid and Health Choice Programs will be terminated. Providers must submit a re-enrollment application to be reinstated.

NON-EMERGENCY MEDICAL TRANSPORTATION (NEMT) PROVIDER ENROLLMENT

As required by the Affordable Care Act, any vendor who provides NEMT services must enroll as a Medicaid provider through NCTracks, the Medicaid Management Information System. As enrolled Medicaid providers, vendors will no longer be reimbursed by the County Department of Social Services (DSS). However, they are required to contract with the County DSS. The vendors will bill for transportation services through NCTracks.

Effective Sept. 1, 2016, NEMT vendors are able to submit claims in NCTracks.

ENROLLMENT OF ORDERING, PRESCRIBING OR REFERRING PROVIDERS

Attending, rendering, ordering, prescribing or referring providers must be enrolled in NC Tracks effective Nov. 1, 2016. Providers are encouraged to submit enrollment applications now. This will ensure that claims are not pended on Nov. 1, 2016 when the provider is not enrolled in Medicaid or NCHC.

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