NC Medicaid Bulletin

October 2019

All Providers

Physicians, Physician Assistants and Nurse Practitioners

Hospital Providers

Durable Medical Equipment Providers

Adult Care Home Providers

ATTENTION: ALL PROVIDERS

Procedures for Prior Authorization of Synagis® (palivizumab) for Respiratory Syncytial Virus Season 2019-2020

The clinical criteria used by NC Medicaid for the 2019-2020 Respiratory Syncytial Virus (RSV) season are consistent with guidance published by the *American Academy of Pediatrics (AAP): 2018 – 2021 Report of the Committee on Infectious Diseases, 31st 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, 2019, through March 31, 2020. Providers are encouraged to review the AAP guidance prior to the start of the RSV season.

On Feb. 1, 2020, NC Medicaid will transition some populations from fee-for-service to managed care statewide. Coverage of Synagis will transition to the Medicaid Managed Care Prepaid Health Plan (PHP) selected by or assigned to the beneficiary. Beginning Feb. 1, 2020, providers will only use the documentforsafety.org web-based process to submit a prior authorization request for coverage of Synagis or complete a dose request to obtain the medication for beneficiaries with traditional Medicaid fee-for-service (now known as Medicaid Direct) coverage.

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
    - Infants in their first year of life with a diagnosis of:
      - 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,
      - Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airway because of ineffective cough.

    Note: Infants in the first year of life with cyanotic heart disease may receive prophylaxis with cardiologist recommendation.

- 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 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 CHD, 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 NC 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. 29, 2019, to allow sufficient time for pharmacies to provide Synagis by Nov. 1, 2019. Payment of a Synagis claim with a date of service before Oct. 29, 2019, and after March 31, 2020, 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 NC 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 separate individual claims will be subject to recoupment. Physicians and pharmacy providers are subject to audits of beneficiary records by NC Medicaid. Maintain Synagis dose authorizations in accordance with required recordkeeping time frames.

Provider Information

Providers without internet access should contact the Medicaid outpatient pharmacy Synagis lead at (919) 527-7658 to facilitate submission of a PA request for Synagis. More information about the Synagis program is available at 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 - Friday from 8 a.m. to 5 p.m. by calling toll free (833) 682-2333 or local: (919) 600-7590. Technical support can assist with provider registration, user name and password issues, beneficiary searches and other registry functions.

GDIT, (800) 688-6696

ATTENTION: ALL PROVIDERS

Clinical Coverage Policy Update

The following new or amended clinical coverage policies are available on NC Medicaid's website:

- 1B, Physician's Drug Program (PDP) – Oct. 1, 2019
- 1B-1, Botulinum Toxin Treatment: Serotype A (Botox, Dysport & Xeomin) Serotype B (Myobloc) (Termination) – Oct. 1, 2019
- 1B-2, Rituximab (Rituxan) (Termination) – Oct. 1, 2019
- 1B-3, Intravenous Iron Therapy (Termination) – Oct. 1, 2019
- 3K-2, Community Alternatives Program for Disabled Adults (CAP/DA) – 10/1/19
- 3D, Hospice Services - Oct. 1, 2019
- 5A-3, Nursing Equipment & Supplies - Oct. 1, 2019
- 9C, Mental Health Drug Management (Termination) - Oct. 1, 2019
- 11A-1, HSCT for Acute Lymphoblastic Leukemia (ALL) – Oct. 1, 2019

- 11A-2, HSCT for Acute Myeloid Leukemia (AML) - Oct. 1, 2019
- 11A-3, HSCT for Chronic Myeloid Leukemia (CML) - Oct. 1, 2019
- 11A-5, Allogeneic HSCT for Genetic Diseases & Acquired Anemias - Oct. 1, 2019
- 11A-6, HSCT in the Treatment of Germ Cell Tumors - Oct. 1, 2019
- 11A-7, HSCT for Hodgkin Lymphoma - Oct. 1, 2019
- 11A-8, HSCT for Multiple Myeloma, POEMS, & Primary Amyloidosis - Oct. 1, 2019
- 11A-9, Allogeneic HSCT for Myelodysplastic Syndromes & Myeloproliferative Neoplasms - Oct. 1, 2019
- 11A-11, Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas – Oct. 1, 2019
- 11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells - Oct. 1, 2019
- 11A-16, HSCT for Chronic Lymphocytic Leukemia (CLL) & Small Lymphocytic Lymphoma (SLL) – Oct. 1, 2019
- 11A-17, CAR-T Cell Therapy - Oct. 1, 2019

These policies supersede previously published policies and procedures.

Proposed new or amended Medicaid and NC Health Choice clinical coverage policies are posted for comment throughout the month. Visit Proposed Medicaid and NC Health Choice Policies for current posted policies and instructions to submit a comment.

GDIT, (800) 688-6696

ATTENTION: ALL PROVIDERS

Sterilization Consent Form

Providers were notified in the August Medicaid bulletin that as of May 1, 2019, the sterilization consent form was updated with an expiration date of April 30, 2022. The sterilization consent form found on the U.S. Department of Health & Human Services (HHS) website has been updated. Providers should now be using this version when submitting the sterilization consent form to the NC Medicaid fiscal agent.

Providers are still obtaining signatures of consent on sterilization forms that are outdated with expiration dates prior to April 30, 2022. Effective Nov. 1, 2019, NC Medicaid will only accept new signatures of consent on the latest version of the consent form with expiration date of April 30, 2022. Therefore, consent forms with a beneficiary signature after Oct. 31, 2019 on an expired consent form will receive a permanent denial. Backdating of signatures on the latest version to a date prior to the new form effective date of May 1, 2019 is not acceptable and will also result in a permanent denial.

Links to latest approved consent form:

https://www.hhs.gov/opa/sites/default/files/consent-for-sterilization-english-updated.pdf (English)

https://www.hhs.gov/opa/sites/default/files/consent-for-sterilization-spanish-updated.pdf (Spanish)

These links can also be accessed from the NC Medicaid website. Providers can access the Sterilization Consent Form by clicking on the Sterilization link and then on the words "Sterilization Consent Form."

Providers may choose to complete the form for each individual or pre-populate information on the site prior to printing the consent form. Signature fields may not be pre-populated. Providers will be notified if a change occurs to the sterilization consent form prior to the expiration date of April 30, 2022.

GDIT, (800) 688-6696 or NCTracksprovider@nctracks.com

ATTENTION: ALL PROVIDERS

Updates to NC Medicaid Electronic Health Record (EHR) Incentive Program

NC-MIPS is Open for Program Year 2019

The NC Medicaid EHR Incentive Payment System (NC-MIPS) is only accepting Program Year 2019 Stage 3 Meaningful Use (MU) attestations.

All eligible professionals (EPs) attesting in Program Year 2019 will be required to attest to Stage 3 MU and use a 2015 Edition of certified EHR technology (CEHRT).

In Program Year 2019, EPs may continue to use a 90-day MU reporting period. The MU reporting period must be from calendar year 2019 and will be any continuous 90-day period in which an EP successfully demonstrates MU of CEHRT. There are only three months left before the end of calendar year 2019. EPs must begin their MU reporting period no later than Oct. 3, 2019 to have 90 days of MU data in 2019.

EPs who were paid for Program Year 2018 using a 90-day patient volume reporting period from calendar year 2018 have the option to use the same patient volume reporting period to attest for Program Year 2019.

The Centers for Medicare and Medicaid Services (CMS) has updated its Promoting Interoperability Program website with Program Year 2019 information and details including the 2019 Medicaid EP specification sheets.

EPs will be attesting to six of 50 clinical quality measures (CQMs). Program Year 2019 CQMs are available for review on the eCQI website.

Attestation assistance is available through detailed attestation guides, an extensive library of answers to Frequently Asked Questions (FAQs), a series of short webinars explaining different aspects of the attestation process and a dedicated help desk. EPs can get free on-site assistance in their office from a coach from their regional area health education center (AHEC). The NC Medicaid EHR Incentive Program contracts with AHEC to provide

technical assistance on meaningful use and the attestation process, so there is no cost to the EP or practice.

Two-Part Attestation Process

All EPs who have 90 days of MU objective data that meets CMS requirements may submit their demographic, license, patient volume and MU objective data in NC-MIPS beginning **May 1, 2019**.

In Program Year 2019, EPs who have successfully attested to MU in a previous program year will be required to use a full calendar year CQM reporting period. Returning meaningful users who would like an early review of requirements, excluding CQMs, may submit their attestation in two parts. Part 1 of the attestation may be submitted **now** through Dec. 31, 2019.

The two-part attestation process does not increase or reduce the information being submitted but allows EPs to complete their attestation in a 12-month window instead of in four months.

Submitting in two parts also allows ample time for EPs to address any attestation discrepancies. These EPs will return to NC-MIPS after Jan. 1, 2020 to submit their CQM data. EPs will not be required to sign or email any documentation for Part 1. The signed attestation packet will be emailed only once, after submission of CQMs in Jan. 2020.

EPs who have only attested to adopt, implement, upgrade (AIU), may use a 90-day CQM reporting period and may submit a complete attestation in NC-MIPS beginning May 1, 2019.

EPs will be automatically directed to the appropriate page in NC-MIPS.

For more information on the two-part attestation process, please email NCMedicaid.HIT@dhhs.nc.gov.

Recent Updates from CMS

The Program Year 2019 Medicaid EP Specification Sheets were updated July 31, 2019 to clarify the requirements for meeting objectives six and seven. The language now reads, "An EP must attest to all three measures and meet the threshold for two measures for this objective. If the EP meets the criteria for exclusion from two measures, they must meet the threshold for the one remaining measure. If they meet the criteria for exclusion from all three measures, they may be excluded from meeting this objective."

On Aug. 2, 2019, CMS issued the Fiscal Year 2020 Inpatient Prospective Payment System (IPPS) and the Long-Term Acute Care Hospital (LTCH) Prospective Payment System (PPS) final rule. This rule changes the minimum MU reporting period for returning meaningful users from a full calendar year to any continuous 90-day period in Program Year 2021.

Reminder on MU Stage 3 Objective 8 Measure 1 (Public Health and Clinical Data Registry Reporting: Immunization Registry Reporting)

To meet Objective 8 Measure 1 (Public Health and Clinical Data Registry Reporting: Immunization Registry Reporting), EPs who administer vaccinations must be in active engagement with the North Carolina Immunization Registry (NCIR). NCIR is capable of accepting the specific standards required to meet the 2015 CEHRT definition and has declared readiness to receive immunization data, so EPs can take an exclusion for this measure only if they do not administer vaccinations.

EPs who wish to participate in Program Year 2019 of the NC Medicaid EHR Incentive Program but who are not yet in active engagement with NCIR, must complete registration with NCIR within 60 days after the start of their MU reporting period. In Program Year 2019, an EP's MU reporting period must begin no later than Oct. 3, 2019 to get 90 days of MU data in calendar year 2019. This means the last day an EP may complete registration with NCIR to meet MU in Program Year 2019 is Dec. 1, 2019, with the 90-day MU reporting period being Oct. 3, 2019 through Dec. 31, 2019.

To begin registering with NCIR, EPs should contact the NCIR Help Desk by phone at (877) 873-6247 or by email at ncirhelp@dhhs.nc.gov. EPs who are not already in active engagement with NCIR should begin this process now if they wish to apply for Program Year 2019 of the NC Medicaid EHR Incentive Program.

General Reminders

EPs who attested with another state should email NCMedicaid.HIT@dhhs.nc.gov prior to attesting with North Carolina for Program Year 2019.

For those practices unsure if a new provider may participate in the NC Medicaid EHR Incentive Program in Program Year 2019, please email the EP's NPI to NCMedicaid.HIT@dhhs.nc.gov and program staff will determine if the provider previously attested with another practice.

GDIT, (800) 688-6696

ATTENTION: ALL PROVIDERS

ICD-10 Update for 2020

The 2020 ICD-10 update will be in place effective Oct. 1, 2019 through Sept. 30, 2020, for provider use. Providers can access the list of ICD-10 codes on the Centers for Medicare and Medicaid Services (CMS) website. https://www.cms.gov/Medicare/Coding/ICD10/

The CMS files include the 2020 new, deleted and revised codes.

To access 2020 ICD-10-CM:

1) https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM.html
2) Select: **2020 Code Descriptions in Tabular Order**
3) Then select: **icd10cm_order-addenda_2020.txt**

To access 2020 ICD-10-PCS

1) https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-PCS.html
2) Select: **2020-10-PCS Order File**
3) Then select: **order_addenda_2020.txt**

GDIT, (800) 688-6696

ATTENTION: ALL PHYSICIANS, PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS

Trastuzumab-anns for Injection, for Intravenous Use (Kanjinti™) HCPCS code J9999 - Not Otherwise Classified, Antineoplastic Drugs: Billing Guidelines

Effective with date of service July 22, 2019, the North Carolina Medicaid and NC Health Choice programs cover trastuzumab-anns for injection, for intravenous use (Kanjinti™) for use in the Physician Administered Drug Program (PADP) when billed with Healthcare Common Procedure Coding System (HCPCS) code J9999 - not otherwise classified, antineoplastic drugs.

Strength/package size(s): For injection: 420 mg lyophilized powder in a multiple-dose vial for reconstitution

Indicated for:

- The treatment of HER2 overexpressing breast cancer
- The treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Recommended Dose: Adjuvant treatment of HER2-overexpressing breast cancer:

- Initial dose of 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Kanjinti, administer 6 mg/kg as an IV infusion over 30−90 minutes every three weeks to complete a total of 52 weeks of therapy.

  OR

- Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30–90 minutes IV infusion every three weeks for 52 weeks.

Metastatic HER2-overexpressing breast cancer:

- Initial dose of 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions.

Metastatic HER2-overexpressing gastric cancer:

- Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.

See full prescribing information for further detail.

For Medicaid and NC Health Choice Billing

- The ICD-10-CM diagnosis code(s) required for billing is/are: HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma:
  C16.0 - Malignant neoplasm of cardia; C16.1 - Malignant neoplasm of fundus of stomach; C16.2 - Malignant neoplasm of body of stomach; C16.3 - Malignant neoplasm of pyloric antrum; C16.4 - Malignant neoplasm of pylorus; C16.5 - Malignant neoplasm of lesser curvature of stomach, unspecified; C16.6 - Malignant neoplasm of greater curvature of stomach, unspecified; C16.8 - Malignant neoplasm of overlapping sites of stomach; C16.9 - Malignant neoplasm of stomach, unspecified;

  HER2 overexpressing breast cancer:
  C50.011 - Malignant neoplasm of nipple and areola, right female breast; C50.012 - Malignant neoplasm of nipple and areola, left female breast; C50.019 - Malignant neoplasm of nipple and areola, unspecified female breast; C50.021 - Malignant neoplasm of nipple and areola, right male breast; C50.022 - Malignant neoplasm of nipple and areola, left male breast; C50.029 - Malignant neoplasm of nipple and areola, unspecified male breast; C50.111 - Malignant neoplasm of central portion of right female breast; C50.112 - Malignant neoplasm of central portion of left female breast; C50.119 - Malignant neoplasm of central portion of unspecified female breast; C50.121 - Malignant neoplasm of central portion of right male breast; C50.122 - Malignant neoplasm of central portion of left male breast; C50.129 - Malignant neoplasm of central portion of unspecified male breast; C50.211 - Malignant neoplasm of upper-inner quadrant of right female breast; C50.212 - Malignant neoplasm of upper-inner quadrant of left female breast; C50.219 - Malignant neoplasm of upper-inner quadrant of unspecified female breast; C50.221 - Malignant neoplasm of upper-inner quadrant of right male breast; C50.222 - Malignant neoplasm of upper-inner quadrant of left male breast; C50.229 - Malignant neoplasm of upper-inner quadrant of unspecified male breast; C50.311 - Malignant neoplasm of lower-inner quadrant of right female breast; C50.312 - Malignant neoplasm of lower-inner quadrant of left female breast; C50.319 - Malignant neoplasm of lower-inner quadrant of unspecified female breast; C50.321 -

Malignant neoplasm of lower-inner quadrant of right male breast; C50.322 - Malignant neoplasm of lower-inner quadrant of left male breast; C50.329 - Malignant neoplasm of lower-inner quadrant of unspecified male breast; C50.411 - Malignant neoplasm of upper-outer quadrant of right female breast; C50.412 - Malignant neoplasm of upper-outer quadrant of left female breast; C50.419 - Malignant neoplasm of upper-outer quadrant of unspecified female breast; C50.421 - Malignant neoplasm of upper-outer quadrant of right male breast; C50.422 - Malignant neoplasm of upper-outer quadrant of left male breast; C50.429 - Malignant neoplasm of upper-outer quadrant of unspecified male breast; C50.511 - Malignant neoplasm of lower-outer quadrant of right female breast; C50.512 - Malignant neoplasm of lower-outer quadrant of left female breast; C50.519 - Malignant neoplasm of lower-outer quadrant of unspecified female breast; C50.521 - Malignant neoplasm of lower-outer quadrant of right male breast; C50.522 - Malignant neoplasm of lower-outer quadrant of left male breast; C50.529 - Malignant neoplasm of lower-outer quadrant of unspecified male breast; C50.611 - Malignant neoplasm of axillary tail of right female breast; C50.612 - Malignant neoplasm of axillary tail of left female breast; C50.619 - Malignant neoplasm of axillary tail of unspecified female breast; C50.621 - Malignant neoplasm of axillary tail of right male breast; C50.622 - Malignant neoplasm of axillary tail of left male breast; C50.629 - Malignant neoplasm of axillary tail of unspecified male breast; C50.811 - Malignant neoplasm of overlapping sites of right female breast; C50.812 - Malignant neoplasm of overlapping sites of left female breast; C50.819 - Malignant neoplasm of overlapping sites of unspecified female breast; C50.821 - Malignant neoplasm of overlapping sites of right male breast; C50.822 - Malignant neoplasm of overlapping sites of left male breast; C50.829 - Malignant neoplasm of overlapping sites of unspecified male breast; C50.911 - Malignant neoplasm of unspecified site of right female breast; C50.912 - Malignant neoplasm of unspecified site of left female breast; C50.919 - Malignant neoplasm of unspecified site of unspecified female breast; C50.921 - Malignant neoplasm of unspecified site of right male breast; C50.922 - Malignant neoplasm of unspecified site of left male breast; C50.929 - Malignant neoplasm of unspecified site of unspecified male breast

- Providers must bill with HCPCS code: J9999 - Not otherwise classified, antineoplastic drugs
- One Medicaid and NC Health Choice unit of coverage is: 10 mg
- The maximum reimbursement rate per unit is: $95.07
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs is/are: 55513-0132-01
- The NDC units should be reported as "UN1."
- For additional information, refer to the January 2012, Special Bulletin, *National Drug Code Implementation Update.*
- For additional information regarding NDC claim requirements related to the PADP, refer to the PADP, Attachment A, H.7 on DHB's website.

- Providers shall bill their usual and customary charge for non-340B drugs.
- PADP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340B participating providers who have registered with the Office of Pharmacy Affairs (OPA). Providers billing for 340B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340B purchasing agreement by appending the "UD" modifier on the drug detail.
- The fee schedule for the PADP is available on NC Medicaid's PADP web page.

GDIT, (800) 688-6696

ATTENTION: ALL PHYSICIANS, PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS

Bevacizumab-awwb injection, for Intravenous Use (Mvasi™) HCPCS Code Q5107 - Injection, Bevacizumab, (Mvasi™), 10 mg: Billing Guidelines

Effective with date of service July 22, 2019, the North Carolina Medicaid and NC Health Choice programs cover bevacizumab-awwb injection, for intravenous use (Mvasi™) for adult use in the Physician Administered Drug Program when billed with HCPCS code Q5107 - Injection, bevacizumab, (Mvasi™), 10 mg.

Strength/Package Size(s): Injection: 100 mg/4 mL (25 mg/mL) in a single-dose vial

Injection: 400 mg/16 mL (25 mg/mL) in a single-dose vial

Indicated for the treatment of:

- Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment.
- Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. (Mvasi is not indicated for adjuvant treatment of colon cancer).
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.
- Recurrent glioblastoma in adults.
- Metastatic renal cell carcinoma in combination with interferon-alfa.
- Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.

Recommended Dose: Metastatic colorectal cancer:

- 5 mg/kg every 2 weeks with bolus-IFL

- 10 mg/kg every 2 weeks with FOLFOX4
- 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first-line bevacizumab product-containing regimen

First-line non-squamous non-small cell lung cancer:

- 15 mg/kg every 3 weeks with carboplatin and paclitaxel

Recurrent glioblastoma:

- 10 mg/kg every 2 weeks

Metastatic renal cell carcinoma:

- 10 mg/kg every 2 weeks with interferon-alfa

Persistent, recurrent, or metastatic cervical cancer:

- 15 mg/kg every 3 weeks with paclitaxel and cisplatin or paclitaxel and topotecan

See full prescribing information for further detail.

For Medicaid and NC Health Choice Billing

- The ICD-10-CM diagnosis code(s) required for billing is/are:

Metastatic colorectal cancer:

C18.0 - Malignant neoplasm of the cecum; C18.1 - Malignant neoplasm of appendix; C18.2 - Malignant neoplasm of ascending colon; C18.3 - Malignant neoplasm of hepatic flexure; C18.4 - Malignant neoplasm of transverse colon; C18.5 - Malignant neoplasm of splenic flexure; C18.6 - Malignant neoplasm of descending colon; C18.7 - Malignant neoplasm of sigmoid colon; C18.8 - Malignant neoplasm of overlapping sites of colon; C18.9 - Malignant neoplasm of colon, unspecified; C19 - Malignant neoplasm of rectosigmoid junction; C20 - Malignant neoplasm of rectum; C21.8 - Malignant neoplasm of overlapping sites of rectum, anus and anal canal;

Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer:

C33- Malignant neoplasm of trachea; C34.00 - Malignant neoplasm of unspecified main bronchus; C34.01 - Malignant neoplasm of right main bronchus; C34.02 - Malignant neoplasm of left main bronchus; C34.10 - Malignant neoplasm of upper lobe, unspecified bronchus or lung; C34.11 - Malignant neoplasm of upper lobe, right bronchus or lung; C34.12 - Malignant neoplasm of upper lobe, left bronchus or lung; C34.2 Malignant neoplasm of middle lobe, bronchus or lung; C34.30 - Malignant neoplasm of lower lobe, unspecified bronchus or lung; C34.31 - Malignant neoplasm of lower lobe, right bronchus or lung; C34.32 - Malignant neoplasm of lower lobe, left bronchus or lung; C34.80 - Malignant

neoplasm of overlapping sites of unspecified bronchus and lung; C34.81 - Malignant neoplasm of overlapping sites of right bronchus and lung; C34.82 - Malignant neoplasm of overlapping sites of left bronchus and lung; C34.90 - Malignant neoplasm of unspecified part of unspecified bronchus or lung; C34.91 - Malignant neoplasm of unspecified part of right bronchus or lung; C34.92 - Malignant neoplasm of unspecified part of left bronchus or lung;

Recurrent glioblastoma:

C71.0 - Malignant neoplasm of cerebrum, except lobes and ventricles; C71.1 - Malignant neoplasm of frontal lobe; C71.2 - Malignant neoplasm of temporal lobe; C71.3 - Malignant neoplasm of parietal lobe; C71.4 - Malignant neoplasm of occipital lobe; C71.5 - Malignant neoplasm of cerebral ventricle; C71.6 - Malignant neoplasm of cerebellum; C71.7 - Malignant neoplasm of brain stem; C71.8 - Malignant neoplasm of overlapping sites of brain; C71.9 - Malignant neoplasm of brain, unspecified;

Metastatic renal cell carcinoma:

C64.1 - Malignant neoplasm of right kidney, except renal pelvis; C64.2 - Malignant neoplasm of left kidney, except renal pelvis; C64.9 - Malignant neoplasm of unspecified kidney, except renal pelvis;C65.1 - Malignant neoplasm of right renal pelvis; C65.2 - Malignant neoplasm of left renal pelvis; C65.9 - Malignant neoplasm of unspecified renal pelvis

Persistent, recurrent, or metastatic cervical cancer:

C53.0 - Malignant neoplasm of endocervix; C53.1 - Malignant neoplasm of exocervix; C53.8 - Malignant neoplasm of overlapping sites of cervix uteri; C53.9 - Malignant neoplasm of cervix uteri, unspecified;

- Providers must bill with HCPCS code: Q5107 - Injection, bevacizumab, (Mvasi), 10 mg
- One Medicaid and NC Health Choice unit of coverage is: 10 mg The maximum reimbursement rate per unit is: $73.16
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs is/are: 55513-0206-01, 55513-0207-01
- The NDC units should be reported as "UN1".
- For additional information, refer to the January 2012, Special Bulletin, National Drug Code Implementation Update.
- For additional information regarding NDC claim requirements related to the PADP, refer to the PADP, Attachment A, H.7 on DHB's website.
- Providers shall bill their usual and customary charge for non-340B drugs.
- PADP reimburses for drugs billed for Medicaid and NC Health Choice beneficiaries by 340B participating providers who have registered with the Office of Pharmacy Affairs (OPA). Providers billing for 340B drugs shall bill the cost that is reflective of

their acquisition cost. Providers shall indicate that a drug was purchased under a 340B purchasing agreement by appending the "UD" modifier on the drug detail.

- The fee schedule for the PADP is available on NC Medicaid's PADP web page.

GDIT, (800) 688-6696

ATTENTION: NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS

Billing Code Update

NC Medicaid has received calls concerning claim denials for some services provided by nurse practitioners (NPs) and physician assistants (PAs).

North Carolina Medicaid has provided instructions to NCTracks on updating the claims processing system. The following procedure code list has been updated recently to include additional NP and PA taxonomies. The newly updated codes are:

33412 (A)	34201 (A)	35570 (A)	

*** Codes marked with an (A) were updated for modifiers 80 and 82**

The Medicaid website has a complete list of previously denied billing codes for NPs, PAs and Certified Nurse Midwives.

Note: Codes currently in process for system updates will be published once system modifications are completed. New code problems will be addressed as North Carolina Medicaid Clinical Policy becomes aware of them.

(MP 19.162 and MP 20.017)

GDIT, (800) 688-6696

ATTENTION: ALL HOSPITAL PROVIDERS

Billing for Nexplanon Implants - Long Acting Reversible Contraceptives (LARCs)

Effective Oct. 1, 2019, two additional ICD-10 codes will be added to the LARC DRG reimbursement retroactive date of Oct. 1, 2018.

Providers must bill with the following HCPCS code, and the appropriate ICD-10 PCS code on the inpatient hospital claim to receive the LARC DRG reimbursement.

HCPCS	**Device**
J7307	**Nexplanon ®**

ICD-10-PCS codes:

OJHD3HZ Insertion of Contraceptive Device into Right Upper Arm

OJHF3HZ. Insertion of Contraceptive Device into Left Upper Arm

Providers may resubmit claims with dates of service on or after Oct. 1, 2018 to receive the appropriate reimbursement.

For additional information regarding reimbursement of Long Acting Reversible Contraceptives (LARCS), refer to the January 2019, Medicaid Special Bulletin.

GDIT, (800) 688-6696

ATTENTION: DURABLE MEDICAL EQUIPMENT PROVIDERS

Updates to Clinical Coverage Policy 5A-3, Nursing Equipment and Supplies

On Oct. 1, 2019, an amended version of Clinical Coverage Policy 5A-3, *Nursing Equipment and Supplies,* was posted to the North Carolina Medicaid website. In addition to correcting numbering, grammatical and style errors, the following changes have been made:

In Subsection **1.2, Categories of Durable Medical Equipment and Medical Supplies**, the reference in the last paragraph to submitting prior authorization (PA) requests for unlisted durable medical equipment (DME) and medical supplies for NC Medicaid beneficiaries over 21 years of age "directly to the Division of Medical Assistance (DMA)" was updated to reflect the current practice of submitting them electronically through NCTracks like all other DME PA requests. This practice became effective Oct. 28, 2018 and was communicated in the Sept. 27, 2018 NCTracks Newsletter.

In Subsection **5.3.2, External Insulin Infusion Pump,** references to the requirement for the DME provider to supply documentation from the manufacturer that a non-functional pump was not repairable, and the warranty had expired when submitting for PA review for a replacement pump, was updated to accept this documentation from the DME provider instead.

In Subsection **5.3.3 Standard Blood Glucose Monitors, Continuous Glucose Monitors and Related Supplies,** language was updated for clarity, and physician assistants and nurse practitioners were added as allowable treating practitioners.

Additionally, this **Note** was added:

> **Note:** Standard BGMs and preferred brand BGM supplies do not require prior authorization. However, prior authorization is required for non-preferred brand BGM supplies. For the National Drug Codes (NDCs) of preferred brand BGM supplies, refer to the DME fee schedule on the NC Medicaid website.

In Subsection **5.3.6 Nutrition,** the requirement for an Oral Nutrition Product Request Form be submitted with PA requests for oral nutrition products was eliminated.

In Subsection **5.3.8 Incontinence, Ostomy, and Urinary Catheter Supplies,** the following **Note** was added to clarify medical necessity and PA requirements for pre-moistened incontinence wipes:

> **Note:** Pre-moistened incontinence wipes must not be billed using A4335 or any other HCPCS code without prior authorization based on EPSDT guidelines or, for beneficiaries over age 21, the procedure outlined in Attachment D: Requesting Unlisted DME and Medical Supplies for Adults. NC Medicaid's Program Integrity Unit and its authorized agents continue to monitor DME provider billing of A4335 for pre-moistened incontinence wipes to ensure compliance with this policy. Any future review revealing non-compliance with Medicaid regulation, rule, and policy may be subject to recoupment.

In Subsection **5.3.9 Miscellaneous Durable Medical Equipment and Medical Supplies,** the medical necessity criteria for sterile and non-sterile gloves was updated to read:

> **Sterile and non-sterile gloves** may be considered medically necessary when used with covered Durable Medical Equipment and Supplies by the beneficiary or to protect the beneficiary from infection. Gloves used by an outside agency for the caregiver's protection, are considered the agency's overhead cost and must not be billed to Medicaid.

In Subsection **5.5 Durable Medical Equipment and Medical Supplies Limitations,** the instructions for submitting a PA request to override a quantity limit or lifetime expectancy was updated to read:

> A PA request for an override of a quantity limit, or lifetime expectancy must contain the usual PA documentation (**Subsections 5.2 and 5.3**) along with the following additional information:
>
> a. The item being requested for an override clearly marked on the CMN/PA form.
> b. The type of override (quantity limit, or lifetime expectancy) clearly stated.
> c. An explanation of the medical necessity for the override from the physician, physician assistant, nurse practitioner, or therapist.
>
> Override PA requests are reviewed for medical necessity as per usual PA review timelines. Override PA review outcomes are communicated to providers and beneficiaries in the same way as a typical PA request.

In Subsection **5.9 Replacing Medical Equipment,** criterion **d.** was added:

> **d.** In cases of wide-spread natural disasters, documentation is accepted from any of the entities listed above or from the NC Division of Emergency Management, Federal Emergency Management Agency, American Red Cross, the National Guard or other appropriate state or local authorities and agencies on the ground in the affected areas.

In Subsection **6.4 Accepting Payment,** language was added to remind providers billing Medicaid beneficiaries that they must comply with North Carolina Administrative Code 10A NCAC 22J .0106.

In **Attachment A: Claims-Related Information, Section C: Code(s)**, the following updates were made:

HCPCS codes **E0776** (IV pole), and **A4435** (ostomy pouch, drainable, high output) were added back to the code list as they were inadvertently left out during a previous update.

Lifetime expectancies for HCPCS codes **A9277** (transmitter; external, for use with interstitial continuous glucose monitoring system) and **A9278** (receiver (monitor); external, for use with interstitial continuous glucose monitoring system) were updated to read: "Per manufacturer's warranty".

The monthly allowable quantity for **A9276** (sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1-day supply) was changed from a 30-day supply to 31-day supply per calendar month.

Quantity limits were added for HCPCS codes **A4927** (gloves, non-sterile, per 100), and for **A4930** (gloves, sterile, per pair) of **4 boxes/month** and **75 pair/month** respectively. Quantities exceeding these limits must be submitted for prior authorization.

Coverage was added for HCPCS code **A7048** (vacuum drainage collection unit and tubing kit).

Quantity limits for HCPCS codes **T4543** (disposable incontinence product, brief/diaper, bariatric, each) and **T4544** (adult sized disposable incontinence product, protective underwear/pull-on, above extra-large, each) were corrected to **192** per month and **200** per month respectively.

Attachment C: Oral Nutrition Product Request Form, became outdated and was deleted.

Attachment E: Requesting Unlisted DME and Medical Supplies for Adults, was re-lettered to **Attachment D,** and the following updates were made:

Criterion **b.** was updated to instruct providers to submit PA requests through NCTracks instead of directly to NC Medicaid clinical policy.

Criterion **c.** was updated to read: Providers may request non-covered, unlisted or restricted items using their identifiable HCPCS code (e.g.: E1012). If no HCPCS code exists, providers may use the miscellaneous combination K0108/W4005 for wheelchair accessories only, and for non-wheelchair items, the miscellaneous combination E1399/W4047.

Criterion **e.** was updated to read: Providers should expect medical necessity reviews using this procedure to be longer than usual.

Criterion **f.** was updated to read: Claims for items approved using this procedure should also be submitted through NCTracks.

Additional Resources

The full text of Clinical Coverage Policy 5A-3 is available at NC Medicaid's Durable Medical Equipment (DME) web page.

GDIT, (800) 688-6696

ATTENTION: ADULT CARE HOME PROVIDERS

Clarification on Family Supplementation of PCS Medicaid Benefit

On Jan. 29, 2013, NC Medicaid issued a memorandum giving guidance on the subject of Guidance for Family Supplementing Payment to the Medicaid Benefit. Several adult care home (ACH) providers have recently referenced this memorandum when inquiring about payment supplements specifically related to the provision of Personal Care Services (PCS) to recipients of special assistance.

Questions received have focused on the ability of ACH providers to charge beneficiaries for additional PCS hours provided to the beneficiary beyond the hours awarded by the independent assessment.

As described in regulation 10A NCAC 13F .0704, providers are prohibited from requiring additional charges to a special assistance beneficiary for State plan PCS defined in NC Clinical Coverage Policy 3L unless the beneficiary or their legal representative voluntarily chooses to personally purchase additional services not covered by Medicaid.

NC Medicaid recognizes there may be circumstances when individuals would like assistance in excess of what is considered medically necessary. Beneficiaries or their legally responsible representative may voluntarily choose to pay for these services; however, any requirement or coercion that special assistance beneficiaries or their legal representative pay for PCS-like services beyond their awarded hours is prohibited.

NC Medicaid LTSS Personal Care Services, (919) 855-4360
