



March 2016 Medicaid Bulletin

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Attention: All Providers

NCTracks Updates

CSC is now CSRA

On Nov. 30, 2015, the government services unit of Computer Sciences Corporation (CSC) joined with SRA International, Inc., to form CSRA. The company has a combined 90 years of experience supporting U.S. federal and state government customers.

The role of CSRA as fiscal agent for the N.C. Department of Health and Human Services (DHHS), specifically the NCTracks claims payment system, remains the same. Over the next few months, providers will see a change to the new name and logo in correspondence, the NCTracks provider portal, and other materials. NCTracks contacts and phone numbers are the same.

Sterilization Consent Forms and Hysterectomy Statement Reminders

Some providers of OB/GYN services have received Sterilization Consent Form and Hysterectomy Statement denials. Many of the denials are due to the absence of several key requirements for approval:

1. N.C. Division of Medical Assistance (DMA) Clinical Coverage Policies (CCP) and Medicaid Bulletin guidelines and regulations are not being followed. CCP 1E-3, *Sterilization Procedures*, and CCP 1E-1, *Hysterectomy*, are located on the [DMA Clinical Policy web page](#).
2. All signatures on both Sterilization Consent Forms and Hysterectomy Statements must be legible. For signatures that are illegible, print the person's name above or below the signature.
3. It is the responsibility of the surgeon to send Sterilization Consent Forms and Hysterectomy Statements to CSRA. Hospitals, anesthesiologists, pathology services and other ancillary providers should **never** send Sterilization Consent Forms and Hysterectomy Statements to CSRA. **The National Provider Identifier (NPI) of the rendering provider (surgeon) will be the only acceptable NPI for Sterilization Consent Forms and Hysterectomy Statements.**
4. Surgeons must submit Sterilization Consent Forms and Hysterectomy Statements within 30 days of the procedure for review and approval.
5. Sterilization Consent Forms and Hysterectomy Statements must **not** be submitted electronically with the claim at this time. Mail Sterilization Consent Forms and Hysterectomy Statements to:

CSRA
P.O. Box 30968
Raleigh NC 27622

Important Note: According to Hysterectomy policy (1E-1), **providers must place the entire Hysterectomy Statement Form on their letterhead** so that all three statements are included on the form when submitting a statement for hysterectomies. A title of “Hysterectomy Statement” must appear above the form area before the actual statement information begins.

2016 Application Fee for Provider

The Centers for Medicare & Medicaid Services (CMS) announced a \$554 application fee for certain providers that are initially enrolling in the Medicaid or N.C. Health Choice (NCHC) programs during calendar year 2016. The types of providers required to pay this fee include, but are not limited to:

- Agencies (case management, behavioral health, home intervention, nursing care, Program for All-Inclusive Care for the Elderly (PACE))
- Ambulatory health care facilities
- Eye and vision services providers
- Hospitals & hospital units
- Laboratories
- Nursing & custodial care facilities
- Nursing service related providers
- Other service providers (case managers, case coordinators, vehicle/home modifications)
- Residential treatment facilities
- Respite care facility
- Suppliers
- Transportation services

This fee is required with enrollment application submitted to NCTracks from Jan. 1, 2016, through Dec. 31, 2016.

For more information about the application fee, see the [Federal Register notice](#) and [NCTracks Provider Portal Frequently Asked Questions web page](#).

Update on 1099s

The 1099s were mailed Thursday, Jan. 21, 2016, to the “1099 Reporting/Pay-To Address” location on the provider file. Those who did not receive a 1099 by February 10 should follow the instructions in [1099 FAQs, question number 5, on the NCTracks Provider Portal](#).

Additional Background Checks during NCTracks Enrollment

The System for Award Management (SAM) is the official U.S. government system that consolidated the capabilities of the:

- Central Contractor Registration (CCR)/FedReg,
- Online Representations and Certifications Application (ORCA), and
- Excluded Parties List System (EPLS).

According to §455.436 (federal database checks), the SAM database must be used to determine if there are final adverse actions that would disqualify an individual or organization from participation in the N.C. Medicaid and N.C. Health Choice (NCHC) programs. This system must be used for applicants, and for individuals and entities the applicant has identified as having a managing relationship and ownership.

As of Jan. 4, 2016, the SAM database check is being applied to enrollment, re-enrollment, re-verification and Manage Change Request (MCR) processes where credentialing is required. NCTracks uses the SAM database to identify applicants who should be disqualified from participation in the N.C. Medicaid or NCHC program because of a final adverse action on an individual or entity with a managing relationship to that applicant.

Note: If a new location is added and a negative SAM database match is found for a managing relationship at that location, the location will be denied. If a managing relationship is added to an existing active location and that managing relationship has a negative SAM database match, the location may be terminated from N.C. Medicaid or NCHC programs. (The provider will receive a termination letter if the location is terminated.)

If an applicant is disqualified as a result of a negative SAM database match, an Application Denial Letter will be emailed to the provider. Termination letters will be sent to the provider's Message Center Inbox and also may be sent by certified mail. The letter will include information regarding the negative SAM database match, if that is the cause of the denial or termination. Information regarding appeals is included in the denial and termination letters.

Additions/Enhancements to Recipient Eligibility Inquiry/Response

On Feb. 1, 2016, additions and enhancements were made to the NCTracks Recipient Eligibility Inquiry/Response process as well as the expanded time frame noted in the [Jan. 20, 2016, announcement](#). These changes affect the Automated Voice Response System (AVRS), NCTracks Provider Portal, and the X12 270/271 transaction.

The secure NCTracks Provider Portal used to verify eligibility has undergone layout changes. Several fields were moved to improve usability, and information was added or modified to enhance the clarity of what is being requested and displayed.

Messages were added to identify beneficiaries with limited or restricted benefits due to their eligibility coverage. Examples of the new responses include:

RESTRICTIVE COVERAGE, INPATIENT SERVICES AT A HOSPITAL ONLY
RESTRICTIVE COVERAGE, EMERGENCY HEMODIALYSIS SERVICES ONLY
PRESUMPTIVE COVERAGE, AMBULATORY PREGNANCY-RELATED SVCS ONLY

The *Health Care Eligibility Benefit Inquiry and Response (270/271) Companion Guide* was updated to reflect these enhancements and posted on the NCTracks Provider Portal [Trading Partner Information page](#). The *AVRS Features Job Aid* under Quick Links on the NCTracks [Provider Portal home page](#) also was updated.

The Computer-Based Training (CBT) course *RCP131 Recipient Eligibility Verification*, and the *Participant User Guide* associated with the Instructor Led Training course *RCP181 Recipient Eligibility Verification*, were updated in SkillPort, the NCTracks Learning Management System.

To access these courses, log on to the secure NCTracks Provider Portal, click Provider Training and navigate to SkillPort. Open the folder labeled **Provider Computer-Based Training (CBT) and Instructor Led Training (ILT)**. The courses can be found in the subfolders labeled **CBTs** and **PUGs**, depending on the format of the course. Refer to the NCTracks [Public Provider Portal Training page](#) of the public Provider Portal for specific instructions on using SkillPort.

CSRA, 1-800-688-6696

Attention: All Providers

Outpatient Hospital and Home Health Providers of Specialized Therapies

Outpatient Specialized Therapy services provided by an outpatient hospital facility or a home health agency are billed to N.C. Medicaid as Institutional Claims. All institutional claims for Outpatient Specialized Therapies are reimbursed based upon the **revenue code** submitted for the date of service, and that revenue code can be applied only once per day. To avoid expending prior authorized (PA) units prematurely, the claim line item must include the date of service and the revenue code. If a CPT code is included, use the **one** CPT code that best describes the procedure performed and indicate only **one** billed unit of service for the CPT code. If more than one CPT code is submitted or if more than one unit of service is billed, then more than one unit of PA will be expended.

Outpatient Specialized Therapies
DMA, 919-855-4260

Attention: All Providers**Maintaining the Security and Accessibility of Records after a Provider Agency Closes**

Notice: This article was originally published in the [February 2013 Medicaid Bulletin](#).

All N.C. Medicaid and N.C. Health Choice (NCHC) providers are responsible for maintaining custody of the records and documentation to support service provision and reimbursement of services by the N.C. Division of Medical Assistance (DMA) for at least six years. See [10A NCAC 22F.0107](#) and Section 7 of the N.C. Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement. The Agreement is part of the enrollment application and may be accessed from the [NCTracks Provider Enrollment web page](#).

Documentation that is required to be maintained by all providers includes clinical service records, billing and reimbursement records, and records to support staff qualifications and credentials (personnel records). **This includes documentation required per federal, state and Medicaid policy requirements that support billing guidelines.**

Clinical service records include, but are not limited to:

- Diagnostic testing results (X-rays, lab tests, psychological assessments, etc.)
- Records from other providers used in the development of care plans
- Nurses' notes or progress notes
- Service orders that authorize treatment
- Treatment service or treatment plans
- Billing and reimbursement records should include beneficiary demographic information.

Providers are **required** to arrange for continued safeguarding of the above-described records in accordance with the record-retention guidelines. Failure to protect consumer or staff privacy by safeguarding records and ensuring the confidentiality of protected health information is a violation of the [Health Insurance Portability and Accountability Act \(HIPAA\)](#) and [NCGS § 108A-80](#) and may be a violation of the [North Carolina Identity Theft Protection Act](#). Violations will be reported to the Consumer Protection Section of the N.C. Attorney General's Office, the Medicaid Investigations Unit of the N.C. Attorney General's Office and/or the U.S. DHHS Office of Civil Rights, as applicable.

The following sanctions, penalties, and fees may be imposed for HIPAA violations:

- Mandatory investigation and penalties for noncompliance due to willful neglect
- Willful neglect: \$50,000 up to \$1.5 million (\$10,000 up to \$250,000 if corrected within 30 days)
- Enforcement by the State Attorney General along with provisions to obtain further damages on behalf of the residents of the State in monetary penalties plus attorney fees and costs as provided for by the Health Information Technology for Economic and Clinical Health (HITECH) Act.

A provider's obligation to maintain the above-described records is independent from ongoing participation in the N.C. Medicaid or NCHC programs and extends beyond the expiration or termination of the Agreement or contract. See [10A NCAC 22F.0107](#) and Section 8 of the DHHS Provider Administrative Participation Agreement. Provider records may be subject to post-payment audits or investigations after an agency closes. Failure to retain adequate and accessible documentation of services provided may result in recoupment of payments made for those services, termination or suspension of the provider from participation with the N.C. Medicaid or NCHC programs and/or referral to the US DHHS Office of Inspector General for exclusion or suspension from federal and state health care programs.

If another provider takes over the functions of a closing entity, maintenance of the closing entity's records for the applicable beneficiaries may be transferred to the new provider, if the new provider agrees to accept custody of such records in writing and a copy of this agreement is provided to DMA upon request. When custody of records is not transferred, the closing providers should send copies of transitional documentation to the providers who will be serving the beneficiary for continuity of care. Consumer authorization should be obtained as necessary. Copies of records may be provided to the beneficiary directly for coordination of care.

DMA must be notified of changes in provider enrollment status, including changes in ownership and voluntary withdrawal from participation in the N.C. Medicaid and NCHC programs, as indicated on the [NCTracks Reporting a Provider Change web page](#). Providers who anticipate closure are required to develop and implement a records retention and disposition plan. The plan must indicate how the records will be stored, the name of the designated records custodian, where the records will be located, and the process to fulfill requests for records. Information must be included on how beneficiaries will be informed of the contact information and the process to request their records. The plan should also designate retention periods and a records destruction process to take place when the retention period has been fulfilled and there is no outstanding litigation, claim, audit or other official action. The plan should be on file with the records custodian.

Program Integrity
DMA, 919-814-0122

Attention: All Providers

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ut-of-State Provider Enrollment

Notice: This article was originally published in the [January 2016 Medicaid Bulletin](#) and again in the [February 2016 edition](#).

Out-of-state providers are required to adhere to all North Carolina rules, regulations, laws and statutes governing healthcare delivery under the N.C. Medicaid and the N.C. Health Choice (NCHC) programs. They are only eligible for time-limited enrollment under the following conditions:

- For the reimbursement of services rendered to N.C. Medicaid or NCHC beneficiaries in response to emergencies or if travel back to North Carolina would endanger the health of the eligible beneficiaries
- For reimbursement of a prior-approved non-emergency service, or,
- For reimbursement of medical equipment and devices that are not available through an enrolled provider located within North Carolina or in the 40-mile border area.

Out-of-state providers must submit a **re-enrollment application** every 365 days in order to continue as N.C. Medicaid or NCHC providers.

Out-of-state providers must wait until the day after their current enrollment period ends – when their provider record is terminated – to begin the re-enrollment process. Many out-of-state providers are attempting to re-enroll using a Managed Change Request (MCR) prior to the end of their current enrollment period. This will not continue provider enrollment. MCRs are used to report changes to the provider record; they do **not** serve as re-enrollment applications.

Providers with questions about the NCTracks online enrollment application can contact the CSRA Call Center at 1-800-688-6696 (phone); 919-851-4014 (fax) or NCTracksprovider@nctracks.com (email).

Provider Services
DMA, 919-855-4050

Attention: Nurse Practitioners, Physician Assistants and Physicians

Asfotase alfa (Strensiq™) HCPCS code J3590: Billing Guidelines

Effective with date of service Nov. 1, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover asfotase alfa (Strensiq) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J3590 Unclassified biologics. Strensiq is currently commercially available in single-use vials as a solution for injection in the following concentrations: 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, and 80 mg/0.8 mL.

Asfotase alfa (Strensiq) is indicated for the treatment of patients with perinatal/infantile-onset or juvenile-onset hypophosphatasia (HPP).

The recommended dose for adults, adolescents, children, infants, and neonates is 2 mg/kg/dose subcutaneously three times/week or 1 mg/kg/dose subcutaneously six times/week. Injection site reactions may limit the tolerability of the 6 times/week regimen. For perinatal/infantile-onset HPP only, the dose may be increased to 3 mg/kg/dose subcutaneously three times/week for insufficient efficacy (e.g., no improvement in respiratory status, growth, or radiographic findings).

Do not use the 80 mg/0.8 mL vial in pediatric patients weighing less than 40 kg because the systemic asfotase alfa exposure achieved with the 80 mg/0.8 mL vial (higher concentration) is lower than that achieved with the other strength vials (lower concentration). A lower exposure may not be adequate for this subgroup of patients.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing asfotase alfa (Strensiq) is E83.39 - Other disorders of phosphorus metabolism.
- Providers must bill Strensiq with HCPCS code J3590 - Unclassified biologics.
- One Medicaid unit of coverage for Strensiq is 1 mg. NCHC bills according to Medicaid units. The maximum reimbursement rate per unit is \$75.60.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Strensiq are 25682-0010-01, 25682-0010-12, 25682-0013-01, 25682-0013-12, 25682-0016-01, 25682-0016-12, 25682-0019-01, and 25682-0019-12.
- The NDC units for asfotase alfa (Strensiq) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate

that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.

- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physicians Assistants and Physicians

Updated Billing Guidelines for Dinutuximab vial (Unituxin™) HCPCS code J9999

This corrects an article published in the November 2015 Medicaid Bulletin, *Dinutuximab Vial (Unituxin™) HCPCS Code J9999: Billing Guidelines*.

The November article stated:

“One Medicaid unit of coverage for Unituxin is one single use vial of 17.5 mg/5 mL. NCHC bills according to Medicaid units. The maximum reimbursement rate per one vial is \$1,620.00000.”

The correct statement is:

“One Medicaid unit of coverage for Unituxin is 1 mL. NCHC bills according to Medicaid units. The maximum reimbursement rate per 1 mL is \$1,603.80.”

CSRA, 1 800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians

Antihemophilic Factor (recombinant), PEGylated powder for injection (Adynovate) HCPCS code J7199: Billing Guidelines

Effective with date of service Nov. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover antihemophilic factor (recombinant), PEGylated powder for injection (Adynovate) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J7199 – Hemophilia clotting factor, not otherwise classified. Adynovate is currently commercially available as single-dose vials in the following nominal potencies of Factor VIII: 250 IU, 500 IU, 1,000 IU and 2,000 IU.

Adynovate is indicated in adolescent and adult patients (12 years and older) with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes and for routine prophylaxis to reduce the frequency of bleeding episodes. Adynovate is not indicated for the treatment of von Willebrand disease.

Calculate the dose of Adynovate based on the empirical finding that one international unit of Adynovate per kg body weight increases the plasma factor VIII level by 2 IU per dL of plasma. Patients vary in their pharmacokinetic (e.g., clearance, half-life, in vivo recovery) and clinical response. Base the dose and frequency of Adynovate on the individual clinical response. Use the following formula to estimate the expected in vivo peak increase in factor VIII level expressed as IU per dL (or % of normal) and the dose to achieve a desired in vivo peak increase in factor VIII level:

- Estimated Increment of factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg)
- Dose (IU) = Body Weight (kg) x Desired factor VIII Rise (IU/dL or % of Normal) x 0.5 (IU/kg per IU/dL)

Dosing for On-demand Treatment and Control of Bleeding Episodes				
Type of Bleeding	Target Factor VIII Level (IU/dL or % of normal)	Dose^a (IU/kg)	Frequency of Dosing (hours)	Duration of Therapy
Minor bleeding	20 – 40	10 -20	12 -24	Until bleeding is resolved
Moderate bleeding	30 – 60	15 – 30	12 -24	Until bleeding is resolved
Major bleeding	60 – 100	30 - 50	8 - 24	Until bleeding is resolved

^a Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)
For routine prophylaxis, administer 40 to 50 international units/kg twice a week and adjust dose based on clinical response.

For intravenous use after reconstitution only.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis code required for billing Adynovate is D66 - Hereditary factor VIII deficiency.
- Providers must bill Adynovate with HCPCS code J7199 – Hemophilia clotting factor, not otherwise classified.
- One Medicaid unit of coverage for Adynovate is 1 IU. NCHC bills according to Medicaid units. The maximum reimbursement rate per unit is \$2.14200.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Adynovate are 00944-4252-02, 00944-4254-02, 00944-4256-02, and 00944-4258-02.
- The NDC units for Adynovate 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800- 688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**C**oagulation Factor X (Human) lyophilized powder for solution for intravenous injection (Coagadex®) HCPCS code J7199: Billing Guidelines

Effective with date of service Dec. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover coagulation Factor X (Human) (Coagadex) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J7199 – Hemophilia clotting factor, not otherwise classified. Coagadex is currently commercially available as single-use vials in nominal potencies of 250 IU and 500 IU of Factor X activity.

Coagadex is indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes and perioperative management of bleeding in patients with mild hereditary Factor X deficiency. Coagadex has not been studied in the perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency.

The dose and duration of Coagadex treatment depends on the severity of the Factor X deficiency, location and extent of the bleeding, and on the patient's clinical condition. However, do not administer more than 60 IU/kg daily. Estimate the expected *in vivo* peak increase in Factor X level expressed as IU/dL (or % of normal) using the following formula:

$$\text{Estimated Increment of Factor X (IU/dL or \% of normal)} = [\text{Total Dose (IU)/Body Weight (kg)}] \times 2$$

The dose to achieve a desired *in vivo* peak increase in Factor X level may be calculated using the following formula:

$$\text{Dose (IU)} = \text{Body Weight (kg)} \times \text{Desired Factor X Rise (IU/dL)} \times 0.5$$

Note: The desired Factor X rise is the difference between the patient's plasma Factor X level and the desired level. The dosing formula is based on the observed recovery of 2 IU/dL per IU/kg.

For on-demand treatment and control of bleeding episodes, infuse 25 IU/kg of Coagadex when the first sign of bleeding occurs. Repeat at intervals of 24 hours until the bleed stops.

For the perioperative management of bleeding, measure post-infusion plasma Factor X levels for each patient before and after surgery, to ensure that hemostatic levels are obtained and maintained.

Pre-surgery

Calculate the dose of Coagadex to raise plasma Factor X levels to 70-90 IU/dL using the following formula:

$$\text{Required dose (IU)} = \text{Body Weight (kg)} \times \text{Desired Factor X Rise (IU/dL)} \times 0.5$$

Post-surgery

Repeat dose as necessary to maintain plasma Factor X levels at a minimum of 50 IU/dL until the patient is no longer at risk of bleeding due to surgery.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis code required for billing Coagadex is D68.2 - Hereditary deficiency of other clotting factors.
- Providers must bill Coagadex with HCPCS code J7199 – Hemophilia clotting factor, not otherwise classified.
- One Medicaid unit of coverage for Coagadex is one IU. NCHC bills according to Medicaid units. The maximum reimbursement rate per unit is \$8.36100.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Coagadex are 64208-7752-01, 64208-7753-01, 64208-7754-01, and 64208-7756-01.
- The NDC units for Coagadex 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians

Daratumumab (Darzalex™) HCPCS code J9999: Billing Guidelines

Effective with date of service Dec. 1, 2015, the N.C. Medicaid and N.C. Health Choice programs cover daratumumab (Darzalex) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999 - Unclassified anti-neoplastics. Darzalex is currently commercially available as a solution in single-dose vials in the following strengths/concentrations: 100 mg/5 mL and 400 mg/20 mL.

Daratumumab (Darzalex) is indicated for the treatment of multiple myeloma in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. Administer pre-infusion medications to reduce the risk of infusion reactions to all patients approximately one hour prior to every infusion of Darzalex.

The recommended dose of Darzalex is 16 mg/kg body weight administered as an intravenous infusion (after dilution) weekly for weeks 1 to 8, every two weeks for weeks 9 to 24, and every four weeks onward until disease progression. Administer Darzalex infusion intravenously at the appropriate infusion rate. Consider incremental escalation of the infusion rate only in the absence of infusion reactions with the previous infusion.

If a planned dose of Darzalex is missed, administer the dose as soon as possible and adjust the dosing schedule accordingly, maintaining the treatment interval. Administer post-infusion medication to reduce the risk of delayed infusion reactions to all patients. Refer to Darzalex package insert for complete information regarding pre- and post-infusion medications, dosing, and administration.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing daratumumab (Darzalex) are C90.00 - Multiple myeloma not having achieved remission and C90.02 - Multiple myeloma in relapse.
- Providers must bill Darzalex with HCPCS code J9999 - Unclassified anti-neoplastics.
- One Medicaid unit of coverage for Darzalex is 1 mg. NCHC reimburses according to Medicaid units.
- The maximum reimbursement rate per unit is \$4,860.00.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Darzalex are 57894-0502-05 and 57894-0502-20.
- The NDC units for daratumumab (Darzalex) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on DMA's website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate

that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.

- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**E**lotuzumab for injection, for intravenous use (Empliciti™) HCPCS code J9999: Billing Guidelines

Effective with date of service Dec. 1, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover elotuzumab (Empliciti™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999 - Unclassified anti-neoplastics. Empliciti is currently commercially available as 300 mg and 400 mg single-dose vials for reconstitution.

Empliciti is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies.

The recommended dose of Empliciti in combination with lenalidomide and dexamethasone is 10 mg/kg intravenously every week for the first two cycles and every two weeks thereafter until disease progression or unacceptable toxicity. Refer to Empliciti package insert for complete information regarding pre- and post-infusion medications, dosing, and administration.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing elotuzumab (Empliciti) are C90.00 - Multiple myeloma not having achieved remission; C90.02 - Multiple myeloma in relapse.
- Providers must bill Empliciti with HCPCS code J9999 - Unclassified anti-neoplastics.
- One Medicaid unit of coverage for Empliciti is 1 mg. The maximum reimbursement rate per unit is \$6.39360.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Empliciti are 00003-2291-11 and 00003-4522-11.
- The NDC units for elotuzumab (Empliciti) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA's PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**Talimogene laherparepvec suspension for intralesional injection
(Imlygic™) HCPCS code J9999: Billing Guidelines**

Effective with date of service Oct. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs covers talimogene laherparepvec (Imlygic™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999, Unclassified antineoplastics. Imlygic is currently commercially available as 10^6 plaque forming units (PFU) per mL or 10^8 PFU per mL in 1mL single-use vials.

Talimogene laherparepvec (Imlygic) is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with malignant melanoma that is recurrent after initial surgery.

The initial recommended dose for talimogene laherparepvec (Imlygic) is up to 4 mL of Imlygic at a concentration of 10^6 (1 million) PFU per mL. The recommended dose for subsequent administrations is up to 4 mL of Imlygic at a concentration of 10^8 (100 million) PFU per mL. The second treatment is administered three weeks after initial treatment. All subsequent treatments (including reinitiation) are to be administered two weeks after the previous treatment. The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. Refer to package insert for specific injection volume base on lesion size.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing talimogene laherparepvec (Imlygic) are:
 - C43.0 - Malignant melanoma of lip;
 - C43.10 - Malignant melanoma of unspecified eyelid, including canthus;
 - C43.11 - Malignant melanoma of right eyelid, including canthus;
 - C43.12 - Malignant melanoma of left eyelid, including canthus;
 - C43.20 - Malignant melanoma of unspecified ear and external auricular canal;
 - C43.21 - Malignant melanoma of right ear and external auricular canal;
 - C43.22 - Malignant melanoma of left ear and external auricular canal;
 - C43.30 - Malignant melanoma of unspecified part of face;
 - C43.31 - Malignant melanoma of nose;
 - C43.39 - Malignant melanoma of other parts of face;
 - C43.4 - Malignant melanoma of scalp and neck;
 - C43.51 - Malignant melanoma of anal skin;
 - C43.52 - Malignant melanoma of skin of breast;
 - C43.59 - Malignant melanoma of other part of trunk;
 - C43.60 - Malignant melanoma of unspecified upper limb, including shoulder;
 - C43.61 - Malignant melanoma of right upper limb, including shoulder;
 - C43.62 - Malignant melanoma of left upper limb, including shoulder;
 - C43.70 - Malignant melanoma of unspecified lower limb, including hip;
 - C43.71 - Malignant melanoma of right lower limb, including hip;

- C43.72 - Malignant melanoma of left lower limb, including hip;
- C43.8 - Malignant melanoma of overlapping sites of skin;
- C43.9 - Malignant melanoma of skin, unspecified;
- C77.0 - Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck;
- C77.1 - Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes;
- C77.2 - Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes;
- C77.3 - Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes;
- C77.4 - Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes;
- C77.5 - Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes;
- C77.8 - Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions; and,
- C77.9 - Secondary and unspecified malignant neoplasm of lymph node, unspecified.
- Providers must bill Imlygic with HCPCS code J9999, Unclassified antineoplastics.
- One Medicaid unit of coverage for Imlygic is 1 million PFU. NCHC bills according to Medicaid units. The maximum reimbursement rate per one unit is \$47.52000.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Imlygic are 55513-0078-01 and 55513-0079-01.
- The NDC units for talimogene laherparepvec Imlygic 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**Sebelipase alfa injection, for intravenous use (Kanuma™) HCPCS code J3590: Billing Guidelines**

Effective with date of service Dec. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover sebelipase alfa (Kanuma™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J3590 - Unclassified biologics. Kanuma is currently commercially available as a 20 mg/10 mL (2 mg/mL) solution in a single-use vial.

Kanuma is indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency. (LAL deficiency is also known as Wolman's disease and cholesteryl ester storage disease [CESD]).

The recommended starting dose for Kanuma in patients with rapidly progressive LAL deficiency presenting within the first 6-months of life is 1 mg/kg administered once weekly as an intravenous infusion. For patients who do not achieve an optimal clinical response, increase to 3 mg/kg once weekly.

The recommended dosage for pediatric and adult patients with LAL deficiency is 1 mg/kg administered once every other week as an intravenous infusion.

For Medicaid Billing and NCHC

- The ICD-10-CM diagnosis codes required for billing sebelipase alfa (Kanuma) is E75.5 - Other lipid storage disorders.
- Providers must bill Kanuma with HCPCS code J3590 - Unclassified biologics.
- One Medicaid unit of coverage for Kanuma is one mg. NCHC bills according to Medicaid units. The maximum reimbursement rate per unit is \$540.00000.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDC for Kanuma is 25682-0007-01.
- The NDC units for sebelipase alfa (Kanuma) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA's PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**Irinotecan liposome injection (Onivyde™) HCPCS code J9999: Billing Guidelines**

Effective with date of service Oct. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover irinotecan liposome injection (Onivyde™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999, Unclassified antineoplastics. Onivyde is currently commercially available as a 43 mg/10 mL (4.3 mg/mL) single dose vial.

Irinotecan liposome injection (Onivyde) is indicated for the treatment of metastatic pancreatic cancer, in combination with 5-fluorouracil (5-FU) and leucovorin, in patients with disease progression after gemcitabine-based therapy. Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

The recommended dose for irinotecan liposome injection (Onivyde) is 70 mg/m² administered by intravenous infusion over 90 minutes every two weeks. The recommended starting dose of Onivyde in patients known to be homozygous for the UGT1A1*28 allele is 50 mg/m² administered by intravenous infusion over 90 minutes. Increase the dose of Onivyde to 70 mg/m² as tolerated in subsequent cycles. Administer Onivyde prior to leucovorin and fluorouracil.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing irinotecan liposome injection (Onivyde) are:
 - C25.0 - Malignant neoplasm of head of pancreas;
 - C25.1 - Malignant neoplasm of body of pancreas;
 - C25.2 - Malignant neoplasm of tail of pancreas;
 - C25.3 - Malignant neoplasm of pancreatic duct;
 - C25.7 - Malignant neoplasm of other parts of pancreas;
 - C25.8 - Malignant neoplasm of overlapping sites of pancreas; and,
 - C25.9 - Malignant neoplasm of pancreas, unspecified.
- Providers must bill Onivyde with HCPCS code J9999, Unclassified antineoplastics.
- One Medicaid unit of coverage for Onivyde is one 43mg/10 mL vial. NCHC bills according to Medicaid units. The maximum reimbursement rate per one unit is \$1749.60000.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDC for Onivyde is 69171-0398-01.
- The NDC units for irinotecan liposome injection (Onivyde) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for

340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.

- The fee schedule for the PDP is available on [DMA's PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**Necitumumab injection, for intravenous use (Portrazza™) HCPCS code J9999: Billing Guidelines**

Effective with date of service Dec. 15, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover necitumumab (Portrazza™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999 - Unclassified anti-neoplastics. Portrazza is currently commercially available as an 800 mg/50 mL (16 mg/mL) solution in a single-dose vial.

Portrazza is indicated in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. Portrazza is not indicated for treatment of non-squamous non-small cell lung cancer.

The recommended dose for Portrazza is 800 mg (absolute dose) administered as an intravenous infusion over 60 minutes on days one to eight of each three-week cycle prior to gemcitabine and cisplatin infusion. Continue Portrazza until disease progression or unacceptable toxicity. See package insert for premedication recommendations and dosage modifications.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing necitumumab (Portrazza) are:
 - 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 or lung;
 - C34.81 - Malignant neoplasm of overlapping sites of right bronchus or lung;
 - C34.82 - Malignant neoplasm of overlapping sites of left bronchus or 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; and,
 - C34.92 - Malignant neoplasm of unspecified part of left bronchus or lung.
- Providers must bill Portrazza with HCPCS code J9999 - Unclassified anti-neoplastics.
- One Medicaid unit of coverage for Portrazza is 1 mg. NCHC bills according to Medicaid units. The maximum reimbursement rate per unit is \$5.40000.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDC for Portrazza is 00002-7716-01.
- The NDC units for necitumumab (Portrazza) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.

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

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians

Idarucizumab injection (Praxbind®) HCPCS code J3590: Billing Guidelines

Effective with date of service Oct. 1, 2015, N.C. Medicaid and N.C. Health Choice (NCHC) programs cover idarucizumab injection (Praxbind®) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J3590, Unclassified biologics. Praxbind is currently commercially available as a 2.5 g/50 mL single-use vial.

Idarucizumab injection (Praxbind) is indicated to reverse the anticoagulant effects of dabigatran (Pradaxa) during emergency surgery or urgent procedures, or in the event of life-threatening or uncontrolled bleeding.

The recommended dose for idarucizumab injection (Praxbind) is 5g (2 vials, each contains 2.5g) administered intravenously as two consecutive infusions or as a bolus injection by injecting both vials consecutively via syringe.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing idarucizumab injection (Praxbind) are:
 - T45.521 - Poisoning by antithrombotic drugs, accidental (unintentional);
 - T45.522 - Poisoning by antithrombotic drugs, intentional self-harm;
 - T45.523 - Poisoning by antithrombotic drugs, assault;
 - T45.524 - Poisoning by antithrombotic drugs, undetermined, and,
 - T45.525 - Adverse effect of antithrombotic drugs.
- Providers must bill Praxbind with HCPCS code J3590, Unclassified biologics.
- One Medicaid unit of coverage for Praxbind is one 2.5 g/50 mL single-use vial. NCHC bills according to Medicaid units. The maximum reimbursement rate per one vial is \$1,890.00.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDC for Praxbind is 00597-0197-05.
- The NDC units for idarucizumab injection (Praxbind) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate

that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.

- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians**T**rabectedin (Yondelis®) HCPCS code J9999: Billing Guidelines

Effective with date of service Nov. 1, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover trabectedin (Yondelis®) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J9999 (Unclassified anti-neoplastics). Yondelis is currently commercially available as 1mg of sterile lyophilized powder in a single-dose vial.

Trabectedin (Yondelis) is indicated for the treatment of unresectable or metastatic liposarcoma or leiomyosarcoma in patients who received a prior anthracycline-containing regimen. Administer premedication of dexamethasone 20 mg intravenously, 30 minutes before each infusion.

The recommended dose for Yondelis is 1.5 mg/m² body surface area as a 24-hour intravenous infusion, every three weeks through a central venous line until disease progression or unacceptable toxicity, in patients with normal bilirubin and AST or ALT less than or equal to 2.5 times the upper limit of normal.

There is no recommended dose of Yondelis in patients with serum bilirubin levels above the institutional upper limit of normal.

Dose modifications are recommended for the following laboratory results or adverse reactions: decreased platelets, decreased ANC, increased total bilirubin, increased AST/ALT/ALP, increased creatine phosphokinase, decreased left ventricular ejection fraction or Grade 3 or 4 other non-hematological adverse reactions. Consult the package insert for multiple dose modifications based on laboratory results or adverse reactions. Once reduced, the dose of Yondelis should not be increased in subsequent treatment cycles. The dose reductions for Yondelis are:

- First dose reduction: Yondelis 1.2 mg/m² every three weeks
- Second dose reduction: Yondelis 1.0 mg/m² every three weeks

Permanently discontinue Yondelis for:

- Persistent adverse reactions requiring a delay in dosing of more than three weeks
- Adverse reactions requiring dose reduction following Yondelis administered at 1.0 mg/m²
- Severe liver dysfunction (all of the following: bilirubin two times the upper limit of normal and AST or ALT three times the upper limit of normal with alkaline phosphatase less than two times the upper limit of normal) in the prior treatment cycle.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing trabectedin (Yondelis) are:
 - C03.9 - Malignant neoplasm of gum, unspecified;
 - C44.90 - Unspecified malignant neoplasm of skin, unspecified;
 - C48.0 - Malignant neoplasm of retroperitoneum;
 - C49.0 - Malignant neoplasm of other connective and soft tissue of head, face and neck;

- C49.10 - Malignant neoplasm of other connective and soft tissue of unspecified upper limb, including shoulder;
 - C49.11 - Malignant neoplasm of other connective and soft tissue of right upper limb, including shoulder;
 - C49.12 - Malignant neoplasm of other connective and soft tissue of left upper limb, including shoulder;
 - C49.20 - Malignant neoplasm of other connective and soft tissue of unspecified lower limb, including hip;
 - C49.21 - Malignant neoplasm of other connective and soft tissue of right lower limb, including hip;
 - C49.22 - Malignant neoplasm of other connective and soft tissue of left lower limb, including hip;
 - C49.3 - Malignant neoplasm of other connective and soft tissue of thorax;
 - C49.4 - Malignant neoplasm of other connective and soft tissue of abdomen;
 - C49.5 - Malignant neoplasm of other connective and soft tissue of pelvis;
 - C49.6 - Malignant neoplasm of other connective and soft tissue of trunk, unspecified;
 - C49.8 - Malignant neoplasm of overlapping sites of connective and soft tissue;
 - C49.9 - Malignant neoplasm of other connective and soft tissue, unspecified
 - C54.0 - Malignant neoplasm of isthmus uteri;
 - C54.1 - Malignant neoplasm of endometrium;
 - C54.2 - Malignant neoplasm of myometrium;
 - C54.3 - Malignant neoplasm of fundus uteri;
 - C54.8 - Malignant neoplasm of overlapping sites of corpus uteri;
 - C54.9 - Malignant neoplasm of corpus uteri, unspecified;
 - C69.60 - Malignant neoplasm of unspecified orbit;
 - C69.61 - Malignant neoplasm of right orbit; C69.62 - Malignant neoplasm of left orbit;
 - C78.6 - Secondary malignant neoplasm of retroperitoneum and peritoneum;
 - C79.2 - Secondary malignant neoplasm of skin;
 - C79.49 - Secondary malignant neoplasm of other parts of nervous system; and, C79.89 - Secondary malignant neoplasm of other specified sites.
- Providers must bill Yondelis with HCPCS code J9999 -Unclassified anti-neoplastics.
 - One Medicaid unit of coverage for Yondelis is one single-dose vial. The maximum reimbursement rate per unit is \$2,916.00.
 - Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDC for Yondelis is 59676-0610-01.
 - The NDC units for trabectedin (Yondelis) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
 - Providers shall bill their usual and customary charge for non-340-B drugs.
 - PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate

that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.

- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physician Assistants and Physicians

Zoster vaccine live (Zostavax®) CPT Code 90736: Billing Guidelines

Effective with date of service Jan 1, 2016, the N.C. Medicaid Program covers zoster vaccine live (Zostavax®) for use in the Physician's Drug Program (PDP) when billed with CPT Code 90736 - zoster (shingles) vaccine (HZV), live, for subcutaneous injection. Zostavax is currently commercially available as a 0.65mL single-dose vial of lyophilized vaccine.

Zoster vaccine live (Zostavax) will be covered by Medicaid for prevention of herpes zoster (shingles) in beneficiaries 60 years of age and older. Zostavax is not indicated for prevention of primary varicella infection (chickenpox) and should not be used in children and adolescents. The recommended dose for zoster vaccine live (Zostavax) is a single 0.65-mL dose subcutaneously in the deltoid region of the upper arm.

For Medicaid Billing

- The ICD-10-CM diagnosis codes required for billing zoster vaccine live (Zostavax) is Z23 - Encounter for immunization. Procedure codes are required to identify the types of immunizations given.
- Providers must bill Zostavax with CPT code 90736 - Zoster (shingles) vaccine (HZV), live, for subcutaneous injection.
- Providers must indicate the number of CPT units
- One Medicaid unit of coverage for Zostavax is a 0.65mL single-dose vial of lyophilized vaccine. The maximum reimbursement rate per one unit is \$202.92570.
- For additional information, refer to the January 2012 Special Bulletin, [National Drug Code Implementation Update](#).
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA's PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Nurse Practitioners, Physicians Assistants and Physicians**Aripiprazole lauroxil injection kits (Aristada™) HCPCS code J3490:
Billing Guidelines**

Effective with date of service Oct. 1, 2015, the N.C. Medicaid and N.C. Health Choice (NCHC) programs cover aripiprazole lauroxil injection kits (Aristada™) for use in the Physician's Drug Program (PDP) when billed with HCPCS code J3490, unclassified drugs. Aristada is currently commercially available in the following size kits:

- 441 mg in 1.6 mL,
- 662 mg in 2.4 mL, and
- 882 mg in 3.2 mL.

Aristada is approved for the treatment of schizophrenia.

The recommended dosing for aripiprazole lauroxil injection kits (Aristada) is 441 mg, 662 mg or 882 mg administered intramuscularly monthly, which corresponds to 300 mg, 450 mg and 600 mg of aripiprazole, respectively. Treatment also may be initiated with the 882 mg dose every six weeks. Administer Aristada either in the deltoid muscle (441 mg dose only) or gluteal muscle (441 mg, 662 mg or 882 mg).

If patient is stabilized on oral aripiprazole, use the following Aristada doses:

- 10mg po per day = 441mg IM per month;
- 15mg po per day = 662mg IM per month;
- 20mg or higher per day = 882mg IM per month.

In conjunction with the first Aristada injection, administer treatment with oral aripiprazole for 21 consecutive days. Dose may be adjusted as needed. When making dose and dosing interval adjustments, the pharmacokinetics and prolonged-release characteristics of Aristada should be considered. The direct administration of a volume less than 0.3 mL is not recommended due to the potential for dosing errors.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis codes required for billing aripiprazole lauroxil injection kits (Aristada) are:
 - F20.0 - Paranoid schizophrenia;
 - F20.1 - Disorganized schizophrenia;
 - F20.2 - Catatonic schizophrenia;
 - F20.3 - Undifferentiated schizophrenia;
 - F20.5 - Residual schizophrenia;
 - F20.81 - Schizophreniform disorder;
 - F20.89 - Other schizophrenia;
 - F20.9 - Schizophrenia, unspecified.

- Providers must bill Aristada with HCPCS code J3490 - Unclassified drugs.
- One Medicaid unit of coverage for Aristada is 1 mg. The maximum reimbursement rate per 1 mg is \$2.58245. NCHC bills according to Medicaid units.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs for Aristada are 65757-0401-03, 65757-0402-03, and 65757-0403-03.
- The NDC units for aripiprazole lauroxil injection kits (Aristada) 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 PDP, refer to the [PDP Clinical Coverage Policy No. 1B](#), Attachment A, H.7 on the DMA website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have [registered with the Office of Pharmacy Affairs \(OPA\)](#). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the “UD” modifier on the drug detail.
- The fee schedule for the PDP is available on [DMA’s PDP fee schedule web page](#).

CSRA, 1-800-688-6696

Attention: Physicians**R**eprocessing of Claims Subject to 3 Percent Rate Reduction:
Frequently Asked Questions (FAQ)

North Carolina state legislation passed in 2013 required a 3 percent rate reduction to physician claims which the N.C. Division of Medical Assistance (DMA) implemented into NCTracks on March 1, 2015. NCTracks reprocessed claims subject to the 3 percent rate reduction in the check writes between April 28 and June 23, 2015. Due to various claim adjudication edits, some claims could not be reprocessed during this first round. The remaining claims required further analysis which caused their reprocessing to be delayed until the Dec. 15, 2015, check write.

As a result of the December 15 check write, there were instances where the original claim was voided because the adjustment was not possible and the entire amount previously paid for the claim was recouped. Some of these reprocessed claims denied for:

- National Correct Coding Initiative (NCCI edits)
- Retroactive changes in eligibility for Medicaid, Medicare, or private insurance, and,
- Service limits.

These denials reflect updates made to the system after the original claim was adjudicated. As a result, the reprocessed claim was affected by a recoupment greater than the 3 percent.

The following information is intended to answer questions providers may have regarding the reprocessing.

1. Why did some of my claims pay at 97 percent and others were denied outright?

The reprocessing was accomplished by voiding the original claim (recouping the original paid amount), and submitting a new claim, to which the reduced rate would apply. In some cases, the new claim denied for other reasons. Examples of those denials include but not limited to NCCI edits; retroactive changes in eligibility for Medicaid, Medicare, or private insurance; and service limits.

2. How do I know why the reprocessed claim denied?

The voided original claim has the Explanation of Benefit (EOB) 06017, but the reprocessed claim has the specific denial EOB. Providers should address the denial of the reprocessed claim the same way they would if it was received on a new claim.

3. Why did the reprocessed claim deny for Third Party Liability (TPL)?

The claim denied because NCTracks received updated recipient eligibility information, after the original claim was processed, indicating that the recipient had third party insurance in effect on the date of service. Thus, when the original claim reprocessed, the other insurance edit caused the adjustment claim to deny.

Since timely filing for providers to bill Medicare and other third party insurers has lapsed, **DMA is going to reprocess all the claims that denied due to TPL (EOB 00094 – TPL Suspect) only in the March 8, 2016, checkwrite** and pay at 97 percent of the original claim amount. DMA will then continue to follow procedures for third party recovery, no further action will be required by the provider.

4. Why did the reprocessed claim deny for an NCCI edit?

Updates made to the NCTracks system that were effective with date of processing will apply to reprocessed claims, regardless of the date of service. The claim denied because NCTracks received updated information on NCCI edits in effect on the date of service, after the original claim was processed. Once the provider corrects the edit error, the claim is eligible to be resubmitted.

5. If I correct the reason for denial and refile the claim to NCTracks, won't there be a timely filing issue?

No. Since there is a denied claim within 18 months, there should not be a timely filing issue.

6. How many more claims will need to be reprocessed before the 3 percent recoupment effort is complete, and when will those efforts occur?

- Approximately 10,000 claims are outstanding due to NPI being updated and no longer billing.
- The reprocessing of physician crossover claims has not taken place; they are anticipated to take place later in 2016.
- The rates for CPT codes that were new in 2015 are being reviewed and may need to be updated to reflect a higher rate.

Additional information on this reprocessing will be provided in subsequent Medicaid bulletins. Those with specific questions related to a claim can call the NCTracks help number **800-688-6696** or email NCTracksprovider@nctracks.com.

**Provider Reimbursement,
DMA, 919-814-0060**

Proposed Clinical Coverage Policies

According to NCGS §108A-54.2, proposed new or amended Medicaid clinical coverage policies are available for review and comment on the DMA website. To submit a comment related to a policy, refer to the instructions on the [Proposed Clinical Coverage Policies web page](#). Providers without Internet access can submit written comments to:

Richard K. Davis
 Division of Medical Assistance
 Clinical Policy Section
 2501 Mail Service Center
 Raleigh NC 27699-2501

The initial comment period for each proposed policy is 45 days. An additional 15-day comment period will follow if a proposed policy is substantively revised as a result of the initial comment period. If the adoption of a new or amended medical coverage policy is necessitated by an act of the N.C. General Assembly or a change in federal law, then the 45- and 15-day time periods will instead be 30- and 10-day time periods.

Checkwrite Schedule

Month	Checkwrite Cycle Cutoff Date	Checkwrite Date	EFT Effective Date
March 2016	03/03/16	03/08/16	03/09/16
	03/10/16	03/15/16	03/16/16
	03/17/16	03/22/16	03/23/16
	03/24/16	03/29/16	03/30/16
April 2016	03/31/16	04/05/16	04/06/16
	04/07/16	04/12/16	04/13/16
	04/14/16	04/19/16	04/20/16
	04/21/16	04/26/16	04/27/16
	04/28/16	05/03/16	05/04/16

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 Division of Medical Assistance
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