

DRAFT

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

1.0 Description of the Procedure, Product, or Service	1
1.1 Definitions	1
1.1.1 Skilled Nursing	1
1.1.2 Nursing Care Activities	2
1.1.3 Substantial	2
1.1.4 Complex.....	2
1.1.5 Continuous.....	2
1.1.6 Significant Change in Condition	2
1.1.7 Primary and Secondary Caregivers	2
2.0 Eligibility Requirements	3
2.1 Provisions	3
2.1.1 General.....	3
2.1.2 Specific	3
2.2 Special Provisions	4
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a.....	4
2.2.2 EPSDT does not apply to NCHC beneficiaries	5
2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6.....	5
3.0 When the Procedure, Product, or Service Is Covered	5
3.1 General Criteria Covered.....	5
3.2 Specific Criteria Covered	5
3.2.1 Specific criteria covered by both Medicaid and NCHC	5
3.2.2 Medicaid Additional Criteria Covered	5
3.2.3 NCHC Additional Criteria Covered	6
3.3 Health Criteria	6
3.3.1 PDN Level 1 Services.....	6
3.3.2 PDN Level 2 Services.....	6
3.4 Amount, Duration, Scope, and Sufficiency of PDN Services	7
3.4.1 Short Term Increase in PDN Services for a Significant Change in Condition.....	7
3.4.2 Therapeutic Leave	8
4.0 When the Procedure, Product, or Service Is Not Covered	8
4.1 General Criteria Not Covered.....	8
4.2 Specific Criteria Not Covered	8
4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC	8
4.2.2 Medicaid Additional Criteria Not Covered	8
4.2.3 NCHC Additional Criteria Not Covered	9
5.0 Requirements for and Limitations on Coverage	10
5.1 Prior Approval.....	10
5.2 Prior Approval Requirements.....	10

**NC Division of Medical Assistance
Private Duty Nursing
for Beneficiaries
Age 21 and Older**

**Medicaid and Health Choice
Clinical Coverage Policy No: 3G-1
Amended Date:**

5.2.1	General.....	10
5.2.2	Specific Criteria.....	10
5.2.3	Requests to Change the Amount, Scope, Frequency, or Duration of Services.....	13
5.2.4	Termination or Reduction.....	14
5.2.5	Changing Service Providers	16
5.2.6	Coordination of Care	18
5.3	Limitations on the Amount, Scope, Frequency, and Duration	19
5.3.1	Unauthorized Hours.....	19
5.3.2	Transportation.....	19
5.3.3	Medical Settings	20
5.3.4	Weaning of a Medical Device	20
6.0	Provider(s) Eligible to Bill for the Procedure, Product, or Service.....	20
6.1	Provider Qualifications and Occupational Licensing Entity Regulations	20
6.2	PDN Service Provider Responsibilities.....	20
6.3	Provider Relationship to Beneficiary	21
6.4	Nurse Supervision Requirements	21
6.5	Provider Certifications	21
	None Apply.....	21
7.0	Additional Requirements	22
7.1	Compliance.....	22
7.2	Documentation Requirements	22
7.2.1	Contents of Records.....	22
7.2.2	Termination of Operations.....	23
7.3	Verification of Eligibility	23
7.4	Qualified Family and Other Designated Caregivers.....	23
7.4.1	Primary, Trained Informal Caregivers.....	23
7.4.2	Training	23
7.4.3	Documenting Competency	23
7.4.4	Emergency Plan of Action.....	23
7.4.5	Evaluation of Health and Safety	23
7.5	Patient Self Determination Act.....	24
7.6	Marketing Prohibition.....	24
8.0	Policy Implementation/Revision Information.....	25
Attachment A: Claims-Related Information.....		29
A.	Claim Type.....	29
B.	International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS).....	29
C.	Code(s)	29
D.	Modifiers	29
E.	Billing Units	30
F.	Place of Service	30
G.	Co-payments.....	30
H.	Reimbursement.....	30

**NC Division of Medical Assistance
Private Duty Nursing
for Beneficiaries Age 21 and Older**

**Medicaid and Health Choice
Clinical Coverage Policy No: 3G-1
Amended Date:**

DRAFT

Attachment B: PDN Forms.....31

DRAFT

This clinical coverage policy has an effective date of September 1, 2020; however, until the end of the public health emergency, the temporary coverage and reimbursement flexibilities enabled by NC Medicaid through a series of COVID-19 Special Medicaid Bulletins will remain in effect.

Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:

- 3A, *Home Health Service*
- 3G-2, *Private Duty Nursing for Beneficiaries under 21 Years of Age*
- 3D, *Hospice*
- 3H-1, *Home Infusion Therapy*
- 3K-1, *Community Alternatives Program for Children (CAP/C)*
- 5A-1, *Physical Rehabilitation Equipment and Supplies*
- 5A-2, *Respiratory Equipment and Supplies*
- 5A-3, *Nursing Equipment and Supplies*
- 8P, *NC Innovations*
- 10C, *Local Education Agencies (LEAs)*
- 10D, *Independent Practitioners Respiratory Therapy Services*

1.0 Description of the Procedure, Product, or Service

Private Duty Nursing (PDN) is substantial, complex, and continuous skilled nursing services that are considered supplemental to the care provided to a beneficiary by the beneficiary's family, foster parents, and delegated caregivers, as applicable. PDN services are provided for beneficiaries who require more individual and continuous care than what is available from a home health service visit. PDN shall be medically necessary for the beneficiary to be covered by NC Medicaid.

PDN services are provided:

- a. Primarily in the beneficiary's private primary residence;
- b. Under the direction of a written individualized plan of care;
- c. As authorized by the beneficiary's attending physician; and
- d. By a registered nurse (RN) or licensed practical nurse (LPN) who is licensed by the North Carolina Board of Nursing (NCBON) and employed by a state licensed and accredited home care agency.

1.1 Definitions

1.1.1 Skilled Nursing

For this policy, nursing services as defined by 10A NCAC 13J.1102 is referred to as "skilled nursing."

Skilled nursing is defined as the assessment, judgment, intervention, and evaluation of interventions by a licensed registered nurse (RN), or a licensed practical nurse (LPN) under the supervision of the RN, and in accordance with the plan of care, in the amount, frequency and duration as outlined in **Section 3.4**. Skilled nursing includes:

DRAFT

- a. Assessing the patient's physical and mental health, including the patient's reaction to illnesses and treatment regimens;
- b. Recording and reporting the results of the nursing assessment;
- c. Planning, initiating, delivering, and evaluating appropriate nursing acts.
- d. Collaborating with other health care providers in determining the appropriate health care for a patient but, subject to the provisions of G.S. 90-18.2, not prescribing a medical treatment regimen or making a medical diagnosis, except under supervision of a licensed physician;
- e. Implementing the treatment and pharmaceutical regimen prescribed by any person authorized by State law to prescribe the regimen.
- f. Providing teaching and counseling about the patient's health.
- g. Reporting and recording the plan for care, nursing care given, and the patient's response to that care.
- h. Providing for the maintenance of safe and effective nursing care, whether rendered directly or indirectly.

Skilled nursing does not include tasks that can be delegated to unlicensed personnel according to NC Board of Nursing Scope of Practice: 21 NCAC 36 .0224 for RN, 21 NCAC 36 .0225 for LPN and 10A NCAC 13J.1102 for In-Home Aide.

1.1.2 Nursing Care Activities

Activities as defined by 21 NCAC 36 .0401. For this policy, Nursing Care Activities are referred to as “tasks.”

1.1.3 Substantial

Substantial means there is a need for interrelated nursing assessments and interventions. Interventions not requiring an assessment or judgment by a licensed nurse are not considered substantial.

1.1.4 Complex

Complex means scheduled, hands-on nursing interventions. Observation in case an intervention is required is not considered complex skilled nursing and is not covered by Medicaid as medically necessary PDN services.

1.1.5 Continuous

Continuous means skilled nursing assessments requiring interventions are performed at least every two (2) hours during the period Medicaid-covered PDN services are provided.

1.1.6 Significant Change in Condition

Significant change means a change in the beneficiary’s status that is not self-limiting, impacts more than one (1) area of functional health status, and requires multidisciplinary review or a revision of the plan of care according to program requirements specified in **Sections 3.0** and **4.0** of this policy.

1.1.7 Primary and Secondary Caregivers

- a. A fully available primary caregiver is a trained, informal caregiver who lives with the beneficiary, is not employed and who is physically and cognitively able to provide care.
- b. A partially available primary caregiver is a trained, informal caregiver who lives with the beneficiary and has verified employment or who has been determined by the Social Security Administration to be unable to work due to a disability and the nature of the

DRAFT

disability is one that limits the ability of that person to provide care to the PDN beneficiary.

- c. A secondary/back-up caregiver is a trained, informal caregiver who is available for instances when the primary informal caregiver is unavailable due to illness, emergency or need for respite.

Note: All parents, guardians, or persons otherwise legally responsible for the beneficiary residing in the home are expected to serve as a trained, informal caregiver.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

a. Medicaid

An eligible Medicaid beneficiary shall be 21 years and older.

Eligibility categories are:

~~1.~~ Fee-for-Service: Beneficiaries covered by Medicaid are eligible to apply for PDN services.

~~2. For Pregnant Women (MPW): Pregnant women may be eligible Medicaid to apply for PDN services if the services are medically necessary for a pregnancy-related condition.~~

~~3.2.~~ Medicare Qualified Beneficiaries (MQB): Medicaid beneficiaries who are Medicare-qualified beneficiaries (MQB) are not eligible for PDN.

~~2.3.~~ Managed Care: Medicaid beneficiaries participating in a managed care program, such as a Medicaid Prepaid Health Plan (PHP), Community Care of North Carolina programs (CCNC), Carolina ACCESS or Eastern Band of Cherokee Indians (ECBI) Tribal Option shall access home services, including PDN, through their primary care physician.

b. NCHC

NCHC beneficiaries are not eligible for Private Duty Nursing (PDN).

DRAFT

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

DRAFT

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/providermanuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/providers/programs-and-services/medical/wellness-visits-and-diagnostic-and-treatment-services>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries Under 21 Years of Age

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply.

3.2.2 Medicaid Additional Criteria Covered

Medicaid shall cover PDN when:

- a. Eligibility criteria in **Section 2.0** are met;
- b. Health criteria in **Section 3.3** are met;
- c. Provided primarily in the primary private residence of the beneficiary. A beneficiary who is authorized to receive PDN services in the primary private residence may make use of the approved hours outside of that setting when normal life activities temporarily take him or her outside that setting. Normal life activities are supported or sheltered work settings, licensed childcare, school and school related activities, and religious services and activities. Normal life activities are not instances when a beneficiary is receiving care in an inpatient facility, outpatient facility, hospital, or residential-type medical setting;
- d. PDN services have been requested and ordered by the beneficiary's attending physician (MD) or Doctor of Osteopathic Medicine (DO) licensed by the North Carolina Board of Medicine and enrolled with Medicaid) on the CMS-485 (Home Health Certification and Plan of Care Form);

DRAFT

- e. Prior approval has been granted by NC Medicaid according to **Section 5.0 of this policy**; and
- f. The beneficiary has at least one (1) trained primary informal caregiver to provide direct care to the beneficiary during the planned and unplanned absences of PDN staff. **If there is no caregiver available to assume this role, PDN cannot be approved.** It is recommended that there be a second trained informal caregiver for instances when the primary informal caregiver is unavailable due to illness, emergency, or need for respite.

3.2.3 NCHC Additional Criteria Covered

None Apply

3.3 Health Criteria

3.3.1 PDN Level 1 Services

To be eligible for Level 1 PDN services, the beneficiary shall:

- a. be dependent on a ventilator for at least eight (8) hours per day, or
- b. meet at least four (4) of the following criteria:
 - 1. unable to wean from a tracheostomy;
 - 2. require nebulizer treatments at least two (2) scheduled times per day and one (1) as needed time per day;
 - 3. require pulse oximetry readings every nursing shift;
 - 4. require skilled nursing or respiratory assessments every shift due to a respiratory insufficiency;
 - 5. require oxygen as needed, also known as pro re nata (PRN) or has PRN rate adjustments at least two (2) times per week;
 - 6. require tracheal care at least daily;
 - 7. require PRN tracheal suctioning. Suctioning is defined as tracheal suctioning requiring a suction machine and a flexible catheter; or
 - 8. at risk for requiring ventilator support;
 - 9. Require at least one non-respiratory skilled nursing intervention that requires more extensive and continual care than can be provided through a home health visit;
 - 10. Evidence of 3 or more organ system deficiencies/failures that requires continual skilled nursing interventions [example: Skin (decubitus ulcers), DI (feeding tube), AND Neuro (TBI, seizures)].

3.3.2 PDN Level 2 Services

Medicaid beneficiaries who meet ALL the criteria for Level 1 nursing services plus at least one (1) of the criteria below may be eligible for additional PDN services – not to exceed the program limit of 112 hours per week:

- a. use of respiratory pacer;
- b. dementia or other cognitive deficits in an otherwise alert or ambulatory recipient;
- c. infusions, such as through an intravenous, Peripherally Inserted Central Catheter (PICC) or central line;
- d. seizure activity requiring use of PRN use of Diastat, oxygen, or other interventions that require assessment and intervention by a licensed nurse.

DRAFT

3.4 Amount, Duration, Scope, and Sufficiency of PDN Services

NC Medicaid shall determine the amount, duration, scope, and sufficiency of PDN services not to exceed 112 hours per week, required by the beneficiary based on a comprehensive review of all the documents listed in **Subsection 5.2.3**, along with the following characteristics of the beneficiary:

- a. Active primary and secondary diagnosis(es);
- b. Overall health status (i.e. mobility, nutrition, recent hospitalizations);
- c. Level and type of technology dependency;
- d. Amount and frequency of specialized skilled nursing interventions required;
- e. Amount of caregiver assistance available. NC Medicaid reserves the right to request verification of each caregiver’s employment schedule annually, and as deemed appropriate by NC Medicaid. Allowances are not for second jobs, overtime, or combination of work and school, when the additional hours cause the policy limit to be exceeded;

Hours are approved on a per-week basis beginning 12:01 a.m. Sunday and ending at 12:00 a.m. Saturday. A beneficiary may use the hours as they choose within the week. It is the responsibility of the beneficiary and caregiver to schedule time to ensure the health and safety of the beneficiary. Additional hours are not approved because the family planned poorly and ‘ran out’ before the end of the week. The hours approved are based on the needs of the beneficiary and caregiver availability, not the needs of other individuals residing in the home.

Note: Unused hours of services shall not be “banked” for future use or “rolled over” to another week.

Approved hours are determined as follows:

Informal Caregiver Availability	Standard PDN Level 1 Approved Hours
Two or more fully available caregivers	Up to 56 hours per week
One fully available caregiver	Up to 84 hours per week
Two or more partially available caregivers	Up to 104 hours per week
One partially available caregiver	Up to 112 hours per week

Note: Expanded PDN Level 2 Services could allow for up to an additional 14 hours per week – as long as that total does not exceed the program maximum of 112 hours per week.

3.4.1 Short Term Increase in PDN Services for a Significant Change in Condition

A short-term increase (STI) in PDN services is limited to a maximum of six (6) calendar weeks and shall be approved by NC Medicaid prior to implementation. The PDN service provider shall submit the DMA-3511 (PDN Change Request Form) and supporting documentation to NC Medicaid at least 5 business days prior to initiating the STI. The amount and duration of the short-term increase is based on medical necessity and approved by NC Medicaid’s PDN Nurse Consultant.

DRAFT

Medicaid shall cover a short-term increase in PDN service when the beneficiary meets ONE of the following significant changes in condition:

- a. New tracheostomy, ventilator, or other life-sustaining medical technology need immediately post discharge, to accommodate the transition and the need for training of informal caregivers. Services generally start at a higher number of hours and are weaned down to previously approved hours over the course of the six (6) weeks.
- b. An acute, temporary change in condition causing increased amount and frequency of nursing interventions.
- c. A family emergency such as an acute change in the primary caregiver's ability to physically and/or cognitively provide care, or when the secondary caregiver is in place but requires additional support because of less availability or need for reinforcement of training.

3.4.2 Therapeutic Leave

Therapeutic leave and/or vacation requests (not for medical purposes such as an out-of-state hospitalization) shall be ordered by the beneficiary's attending physician. Approval of therapeutic leave is limited to 14 days per calendar year and shall not exceed current approved hours. The attending physician shall indicate the beneficiary is able to travel safely and requires nursing care during leave time. The necessity for a nurse to travel with the beneficiary and caregiver(s) shall be documented in the attending physician-signed order.

The PDN service provider shall submit the attending physician-signed order for therapeutic leave to NC Medicaid for review at least five (5) business days prior to the therapeutic leave request.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

Medicaid shall not cover PDN if any of the following are true:

- a. the beneficiary is receiving medical care in a hospital, nursing facility, outpatient facility, or residential-type medical setting where licensed personnel are employed;

DRAFT

- b. the beneficiary is a resident of an adult care home, group home, family care home, or nursing facility;
- c. the service is for custodial, companion, respite services (short-term relief for the caregiver) or medical or community transportation services;
- d. the nursing care activities rendered can be delegated to unlicensed personnel (Nurse Aide I or Nurse Aide II), according to 21 NCAC 36.0401 and 21 NCAC 36.0221(b);
- e. the purpose of having a licensed nurse with the beneficiary is for observation or monitoring in case an intervention is required;
- f. the service is for the beneficiary or caregiver to go on overnight trips away from the beneficiary's private primary residence. **Note:** Short-term absences from the primary private residence that allow the beneficiary to receive medical care in an alternate setting for a short period of time, and therapeutic leave requests may be allowed if the following are true: PDN is not provided for respite, PDN is not provided in an institutional setting, and when PDN is provided according to nurse and home care licensure regulations;
- g. services are provided exclusively in the school
- h. the beneficiary does not have informal caregiver support available as per **Subsection 3.2.2.f;**
- i. the beneficiary is receiving home health nursing services or respiratory therapy treatment (except as allowed under clinical coverage policy 10D, *Independent Practitioners Respiratory Therapy Services*) during the same hours of the day as PDN;
- j. the beneficiary is receiving infusion therapy services as found under the clinical coverage policy 3H-, *Home Infusion Therapy (HIT)* program; or
- k. the beneficiary is receiving hospice services as found under clinical coverage policy 3D, *Hospice Services*, except as those services may apply to children under the Patient Protection and Affordable Care Act.
H.R.3590
- l. the beneficiary is receiving services from other formal support programs (such as NC Innovations) during the same hours of the day as PDN.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 - 1. No services for long-term care.
 - 2. No nonemergency medical transportation.
 - 3. No EPSDT.
 - 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

DRAFT

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Medicaid shall require prior approval (PA) before rendering Private Duty Nursing (PDN) Services.

Note: Prior approval is granted based on medical necessity and caregiver availability only. It does not guarantee payment or ensure beneficiary NC Medicaid eligibility on the date of service. All service requirements shall be met for the PDN service provider to receive payment.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Personnel the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific Criteria

5.2.2.1 Initial Referral Process

A medical provider shall refer a potential beneficiary to a PDN service provider to initiate the initial referral review process. The PDN service provider shall complete a comprehensive assessment within 48 hours of the start of care (SOC) date and enter a request for PA by submitting documents (as listed in **Subsection 5.2.2.2**) for initial referral provisional review.

5.2.2.2 Documentation Requirements for Initial Referral Provisional Review

Initial provisional approval may be granted for 30-calendar days only, pending receipt of additional documentation (refer to **Subsection 5.2.2.3**). NC Medicaid shall complete a clinical review for PDN services upon receipt of the following required documents dated within the last sixty (60) days:

- a. DMA-3508 (PDN Referral Form) signed by the attending physician AND
- b. Recent history and physical (H&P).
 1. If the beneficiary is being discharged from the hospital, submit current hospital progress notes or a hospital discharge summary;
 2. If the beneficiary is being referred from the community, submit clinic notes from the last two office visits pertaining to the referring diagnosis;
 3. Private health insurance coverage or denial documentation for current approval period, if applicable.

PDN service providers shall indicate in their submitted documents all caregivers available to supplement care and the status of training provided.

Note: Once all required documentation is received, NC Medicaid shall conduct a clinical review for initial referral provisional PDN services. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

DRAFT

If the initial referral request is received after the start of care date, NC Medicaid shall only consider approval of PA from the date of request submission.

5.2.2.3 Documentation Requirements for Initial Referral Continuation Review

Continuation approval is granted for the remainder of the 180-day PA period. The PDN service provider shall submit the following documentation by PA day 30 to include:

- a. Attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form);
- b. Employment verification documentation to include one of the following:
 1. A statement on company letterhead signed by a supervisor or representative from the employer's Human Resources Department detailing the employee's current status of employment (such as active or on family medical leave), typical work schedule, and employer's contact information; or
 2. Pay stubs for the last two (2) months of employment; or
 3. If a caregiver is self-employed, a Federal Schedule C (Form 1040), or the Profit or Loss from Business (Sole Proprietorship) form from the most recent tax return may be used; and
- c. PDN service provider's consent to treat document.

Additional documentation shall be required throughout the first 180-day authorization period to validate the initial request for PDN. The DMA-3509 (PDN Medical Update Form) and attending physician-signed CMS-485 shall be uploaded every 60 days.

A verbal order and date signed by RN if CMS-485 (Locator 23) if not signed by the attending physician in advance of the certification period is acceptable. All attending physician signed 485's for the 180-day certification period shall be uploaded before the PA expiration date.

- a. By PA day 60: DMA-3509 (PDN Medical Update Form) and attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) shall be submitted.
- b. By PA day 120: DMA-3509 (PDN Medical Update Form) and attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) shall be submitted.

If the beneficiary experiences a significant change of condition, NC Medicaid shall re-evaluate services at that time (Refer to Subsection 5.2.2.7).

Note: Once all required documentation is received, NC Medicaid shall complete the clinical review for initial referral continuation of PDN services. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the required documentation for initial continuation is received after the provisional approval timeframe has ended, NC Medicaid shall only consider extending continuation approval of PA from the date of request submission.

DRAFT

5.2.2.4 Plan of Care

The attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) shall document:

- a. All pertinent diagnoses, including the beneficiary's mental status;
- b. The type of services, medical supplies, and equipment ordered;
- c. The number of hours of PDN per day and number of days per week, according to 42CFR 409.43 Plan of Care Requirements;
- d. The primary payor source of PDN hours to include private health insurance coverage if applicable;
- e. Specific assessments and interventions to be administered by the nurse;
- f. Individualized nursing goals with measurable outcomes;
- g. Verbal order and date signed by RN if CMS-485 (Locator 23) is not signed by the attending physician in advance of the certification period is acceptable;
- h. The beneficiary's prognosis, rehabilitation potential, functional limitations, permitted activities, nutritional requirements, medications-indicating new or changed in last 30 calendar days, and treatments;
- i. Teaching and training of caregivers;
- j. Safety measures to protect against injury;
- k. Disaster plan in case of emergency or natural occurrence; and
- l. Discharge plans individualized to the beneficiary.

Note: The PA period is a maximum of 180 days, but the attending physician signed CMS-485 and DMA-3509 (PDN Medical Update Form) shall be uploaded every 60 days. A verbal order and date signed by RN if CMS-485 (Locator 23) is not signed by the attending physician in advance of the certification period is acceptable. All attending physician-signed 485s for the 180-day certification period shall be uploaded before the PA expiration date.

5.2.2.5 Reauthorization Process and Documentation Requirements

To recertify for PDN services, the PDN service provider shall enter a request for reauthorization and submit the following required documents to NC Medicaid at least 15 business days prior to the end of the current approved PA period:

- a. A copy of the CMS-485 (Home Health Certification and Plan of Care Form) signed and dated by the attending physician;
- b. DMA-3509 (PDN Medical Update Form);
- c. Nursing notes from the last authorization period. At least five (5) non-consecutive calendar days are required;
- d. Private health insurance coverage or denial documentation for current approval period, if applicable;
- e. Missed shift hours report during the previous 180-day authorization period.

The PA period is a maximum of 180 days. The attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) and DMA-3509 (PDN Medical Update Form) shall be uploaded every 60 days. A verbal order and date signed by

DRAFT

RN if CMS-485 (Locator 23) is not signed by the attending physician in advance of the certification period is acceptable. All attending physician signed 485's for the 180-day certification period shall be uploaded before the PA expiration date:

- a. By PA day 60: DMA-3509 (PDN Medical Update Form) and attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) shall be submitted.
- b. By PA day 120: DMA-3509 (PDN Medical Update Form) and attending physician-signed CMS-485 (Home Health Certification and Plan of Care Form) shall be submitted.

PDN service provider(s) shall disclose the total number of missed shift hours during the previous 180-day authorization period, on the DMA-3509 (PDN Medical Update form), with an attestation that this report accurately reflects the missed shift hours and shall be provided to the beneficiary or legal guardian upon request.

At NC Medicaid's discretion, an in-home assessment may be performed by NC Medicaid or its designee. NC Medicaid reserves the right to request additional records, including hospitalization records and discharge summary, medical records from attending physician or medical specialists, and any other medical records.

NC Medicaid reserves the right to verify caregiver's employment schedule annually and as deemed appropriate by NC Medicaid.

Note: Once all required documentation is received, NC Medicaid shall conduct the clinical review for reauthorization. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the request for reauthorization is received after the beginning of the new authorization period, NC Medicaid shall only consider approval of PA from the date of request submission.

5.2.2.6 Re-Evaluation during the Approved Period

The PDN service provider shall notify NC Medicaid of a significant change in the beneficiary's medical status, such as a significant improvement or decline, a change in caregiver availability, or change in private health insurance coverage within five (5) business days. NC Medicaid shall re-evaluate services at that time.

Note: The DMA-3511 (PDN Change Request Form) shall be submitted to NC Medicaid within five (5) business days prior to the requested change in care date.

5.2.3 Requests to Change the Amount, Scope, Frequency, or Duration of Services

Any requests to change the amount, scope, frequency, or duration of services shall be ordered by the attending physician and approved by NC Medicaid prior to implementation. The DMA-3511 (PDN Change Request form) with additional required documentation shall be uploaded to the current PA, and NC Medicaid shall be notified.

DRAFT

5.2.3.1 Temporary Decreases

Requests to decrease the amount, scope, frequency, or duration of services for seven (7) days or less, such as over a holiday when additional family members are available to provide care and services, do not require NC Medicaid approval. Previously approved service levels can resume after the family situation returns to the normal routine. The agency shall document the reason for the decrease in services and supportive information, notifying the attending physician as appropriate.

5.2.3.2 Emergency Changes

Sudden changes in the amount, scope, frequency or duration of services are based on true emergent medical necessity of beneficiary or their primary caregiver. Emergency changes initiated outside of regular business hours shall be reported to NC Medicaid the next business day. The written request shall provide specific information regarding changes in the beneficiary's or their primary caregiver's medical condition necessitating the increase and a documented, supplemental verbal order signed by RN. An attending physician-signed order shall be provided to NC Medicaid within five (5) business days.

5.2.4 Termination or Reduction

PDN services may be reduced or terminated by the beneficiary's attending physician, the beneficiary or their legal representative, or NC Medicaid. Important information about the Medicaid Beneficiary Due Process (Appeal Rights) is found on the NC Medicaid website: <https://medicaid.ncdhhs.gov/>.

5.2.4.1 Notification of Termination

The termination process is determined by the following:

- a. If the PDN service provider discharges the beneficiary, this service provider shall submit the DMA-3513 (PDN Discharge Summary Form) to NC Medicaid within five (5) business days.
- b. If the PDN service provider discharges the beneficiary from Medicaid coverage because there is another source of nursing care coverage, this provider shall notify NC Medicaid and submit the DMA-3513 (PDN Discharge Summary Form) within five (5) business days. The notification shall include the last date that PDN services were provided and can be billed to Medicaid and the name of the other source of coverage.
- c. If the attending physician discharges the beneficiary, this PDN service provider shall provide to NC Medicaid, within five (5) business days, the attending physician's order to terminate PDN services and the DMA-3513 (PDN Discharge Summary Form). **The decision of the beneficiary's attending physician and/or the PDN service provider to discharge the beneficiary cannot be appealed to NC Medicaid.**
- d. If services are terminated as a result of the beneficiary's loss of NC Medicaid eligibility, or if no PDN services are provided during the 30 consecutive days for any reason including hospitalization, then the

DRAFT

prior approval process shall be initiated again as outlined in **Subsections 5.1 and 5.2.**

PDN service providers shall notify NC Medicaid when a beneficiary is hospitalized for 30 days or greater.

- e. NC Medicaid shall terminate PDN if a review of services shows NC Medicaid eligibility, policy criteria and/or medical necessity is not met. NC Medicaid of its designee shall provide notice of an adverse decision in writing to the beneficiary/legal representative that includes information about appeal rights.

Note: PDN service provider(s) shall disclose the final number of missed shift hours during the authorization period, on the DMA-3513 (PDN Discharge Summary Form), with an attestation that this report accurately reflects the missed shift hours and shall be provided to the beneficiary or legal guardian upon request.

5.2.4.2 Notification of Reduction

The reduction of PDN services process is determined by the following:

- a. If the PDN service provider reduces PDN services: this provider shall notify NC Medicaid and submit within five (5) business days, a copy of the attending physician's order to reduce services and the DMA-3511 (PDN Change Request Form).
- b. If the attending physician reduces PDN services: this PDN service provider shall notify NC Medicaid and submit within five (5) business days, the attending physician's order to reduce services and the DMA-3511 (PDN Change Request Form).
- c. If NC Medicaid initiates the reduction of PDN services because it has determined that the beneficiary, no longer meets the previous level of policy criteria and/or medical necessity (refer Subsection 3.2.2). NC Medicaid may request additional information from the PDN service provider. In the event the additional information is not provided within 10 business days of the request for additional information (or other time frame agreed upon by the PDN service provider and NC Medicaid nurse consultant), NC Medicaid shall proceed with the reduction of services.

DRAFT

5.2.5 Changing Service Providers

Requests to change PDN service providers may occur as a result of a beneficiary's exercising freedom of choice.

5.2.5.1 Transfer of Care Between Two Branch Offices of the Same Agency Process.

The **initiating PDN service provider branch office** shall facilitate the change by coordinating the transfer of care with the beneficiary's attending physician, the beneficiary or legal guardian and the current PDN service provider branch office.

The **initiating PDN service provider** shall also notify NC Medicaid and submit required documentation at least five (5) business days prior to branch transfer. The **initiating PDN service provider branch office** is responsible for submitting an attending physician-signed order with a new PA entry.

Note: The attending physician-signed order may be submitted as either an addendum to the current PDN service provider's CMS-485 (Home Health Certification and Plan of Care Form), and/or an updated, attending physician-signed CMS-485. Either option shall include the new PDN service provider's name, address, and National Provider Identifier (NPI) number.

The **current PDN service provider branch office** shall upload the DMA-3513 (PDN Discharge Summary Form) to their approved PA.

Both PDN service providers shall ensure that written and verbal orders are verified and documented according to 10A NCAC 13J, The Licensing of Home Care Agencies.

5.2.5.1 Transfer of Care Between Two Different Agencies Process

The **initiating PDN service provider** shall facilitate the transfer process by coordinating the transfer of care with the beneficiary's attending physician, the beneficiary or legal guardian and the current PDN service provider.

Transfer provisional approval may be granted for 30-calendar days only, pending receipt of additional documentation (refer to **Subsection 5.2.5.1**).

5.2.5.2 Documentation Requirements for Transfer Provisional Review

The **initiating PDN service provider** shall submit the following documents for a transfer provisional review:

- a. DMA-3508 (PDN Referral Form) signed by the attending physician;
- b. Private health insurance coverage or denial documentation for prior approval period, if applicable.

DRAFT

Required documentation shall be submitted to NC Medicaid at least five (5) business days prior to the requested start of care date.

Note: Once all required documentation is received, NC Medicaid shall conduct a review for transfer of PDN service hours. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the required documentation for transfer continuation is received after the transfer provisional approval timeframe has ended, NC Medicaid shall only consider extending continuation approval of PA from the date of request submission.

5.2.5.3 Documentation Requirements for Transfer Continuation Approval

Transfer continuation approval may be granted for the remainder of the 180-day PA period. The **initiating PDN service provider** shall submit the following documentation by PA day 30 to include:

- a. Attending physician-signed CMS 485 (Home Health Certification and Plan of Care Form);
- b. PDN service provider's consent to treat document.

Note: Once all required documentation is received, NC Medicaid shall complete the review for transfer of PDN service hours. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

5.2.5.4 Sharing Care Between Two or More Different Agencies Process

The **initiating PDN service provider(s)** shall facilitate the change by coordinating shared care with the beneficiary's attending physician, the current PDN service provider(s), and the beneficiary or legal guardian. Provisional approval may be granted for 30-calendar days only. This is a provisional approval pending receipt of additional documentation (refer to **Subsection 5.2.5.3.2**).

5.2.5.5 Documentation Requirements for Shared Provisional Review

The **initiating PDN service provider(s)** shall submit the following documents for shared provisional review:

- a. DMA-3508 (PDN Referral Form) signed by the attending physician;
- b. DMA-3512 (PDN Shared Case Form);
- c. Private health insurance coverage or denial documentation for prior approval period, if applicable.

Required documentation shall be submitted to NC Medicaid at least five (5) business days prior to the requested start of care date.

NC Medicaid shall process the continuation approval for PDN services within 5 business days of the receipt of all required information from the PDN service provider.

DRAFT

Note: Once all required documentation is received, NC Medicaid shall conduct a review for shared PDN service hours. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the request for shared hours is received by the initiating PDN service provider(s) after the start of care date, NC Medicaid shall only consider approval of PA from the date of request submission.

5.2.5.6 Documentation Requirements for Shared Continuation Review

Shared continuation approval may be granted for the remainder of the 180-day PA period. The **initiating PDN service provider** shall submit the following documentation by PA day 30 to include:

- a. Attending physician-signed CMS 485 (Home Health Certification and Plan of Care Form);
- b. PDN service provider's consent to treat document.

Note: Once all required documentation is received, NC Medicaid shall complete the review for shared PDN service hours. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the required documentation for shared continuation is received after the shared provisional approval timeframe has ended, NC Medicaid shall only consider extending continuation approval of PA from the date of request submission.

5.2.5.7 Documentation Requirements for Re-distribution of Shared Hours

The PDN service provider initiating the change in shared hours shall facilitate the change by coordinating shared hours with the beneficiary or legal guardian, and submitting the DMA-3512 (PDN Shared Case Form) to the approved PA.

Note: The DMA-3512 (PDN Shared Case Form) shall be submitted to NC Medicaid at least five (5) business days prior to the requested start of care date.

All PDN service providers shall ensure that written and verbal orders are verified and documented according to 10A NCAC 13J, The Licensing of Home Care Agencies.

Note: Once required documentation is received, NC Medicaid shall complete the review for re-distribution of shared hours. Incomplete or omitted documentation is handled as an incomplete request and may result in denial of the PA request.

If the request for re-distribution of shared hours is received after the start of care date of the re-distribution, NC Medicaid shall only consider extending continuation approval of PA from the date of request submission.

5.2.6 Coordination of Care

The beneficiary's attending physician and the PDN service provider are responsible for monitoring the beneficiary's care and initiating any appropriate changes in PDN services.

DRAFT

5.2.6.1 Transfers Between Health Care Settings

If a beneficiary is placed in a different health care setting due to a change in his or her medical condition, the PDN service provider shall notify NC Medicaid within 5-business days.

5.2.6.2 Drug Infusion Therapy

If a beneficiary requires drug infusion therapy, the Durable Medical Equipment (DME) supplier provides the drug infusion equipment, and drugs are provided through Medicaid's or Medicare's pharmacy coverage. The PDN service provider is responsible for the administration and caregiver teaching of the infusions.

5.2.6.3 Enteral or Parenteral Nutrition

If a beneficiary requires enteral or parenteral nutrition, the Durable Medical Equipment (DME) supplier provides the equipment, supplies, and nutrients. Home Health and Home Infusion would be a duplication of services.

Refer to **Section 4.0** for information on services that are not covered when the beneficiary is receiving PDN services.

5.2.6.4 Home Health Nursing

Home Health nursing services may not be provided concurrently with PDN Services. When a beneficiary requires Home Health medical supplies, the PDN service provider shall provide and bill for those supplies. The PDN service provider is also expected to provide blood draws, wound care, and other home health nursing tasks for a PDN beneficiary.

5.2.6.5 Medical Supplies

Medical supplies are covered as per the criteria for coverage of medical supplies and use of the miscellaneous procedure code for medical supplies defined in clinical coverage policies 3A, *Home Health Services* and 5A, *Durable Medical Equipment* (available here: <https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies/clinical-coverage-policy-index>).

Refer to **Subsection 7.2** for documentation requirements.

5.3 Limitations on the Amount, Scope, Frequency, and Duration

5.3.1 Unauthorized Hours

PDN services provided in excess of the approved amount are the financial responsibility of the PDN service provider.

5.3.2 Transportation

The PDN nurse may not transport the beneficiary. The licensed nurse may accompany or travel with the beneficiary if medically necessary as defined in **Subsection 3.2** and **Subsection 3.4.2**, when his or her normal life activities require that the beneficiary access the community within the NC Medicaid approved time scheduled for PDN services.

DRAFT

5.3.3 Medical Settings

PDN is not covered for a beneficiary in a hospital, nursing facility, outpatient facility, or residential-type medical setting where licensed personnel are employed and have prescribed responsibility for providing care for the designated beneficiary.

5.3.4 Weaning of a Medical Device

NC Medicaid or its designee may authorize PDN services for a brief period after the beneficiary no longer requires the medical device to compensate for loss of a vital body function. Within 10 business days, the PDN service provider shall notify NC Medicaid and submit the DMA -3511 (PDN Change Request Form), required supporting documentation and updated physician's orders and interventions. Continuation of PDN services shall then be re-evaluated by NC Medicaid.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the PDN service provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

PDN services shall be provided by home care agencies accredited with Joint Commission, Community Health Accreditation Partner (CHAP), or Accreditation Commission for Health Care (ACHC); and holding a current license from the N.C. Division of Health Service Regulation (DSHR) or as applicable, Eastern Band of Cherokee providers shall be a Medicare Certified Home Health Agency. The home care agency shall be an enrolled N.C. Medicaid provider approved by NC Medicaid to provide PDN services. Each office of the home care agency providing services shall have an individual N.C. Medicaid PDN National Provider Identifier (NPI) number.

6.2 PDN Service Provider Responsibilities

The PDN service provider is responsible for:

- a. ensuring that qualified and competent licensed nurses are assigned to provide skilled nursing care as required by the plan of care and the services are provided within the nurses' scope of practice as defined by 21 NCAC 36;
- b. ensuring accreditation with Joint Commission, Community Health Accreditation Partner (CHAP), Accreditation Commission for Health Care (ACHC) or federal law, including the IHCA, 25 U.S.C. § 1601, et seq. and/or 42 C.F.R. Part 136 and Section 5006 of the American Recovery and Reinvestment Act (ARRA) of 2009. as appropriate.
- c. ensuring orientation and competency assessment of skills are sufficient to meet the plan of care requirements before assigning the nurse to the beneficiary's care;

DRAFT

- d. ensuring RNs and LPNs have documented continuing education hours, as per NC Board of Nursing;
- e. developing and providing orientation to licensed nurses for policies and procedures consisting of the following:
 1. organizational chart and line of supervision;
 2. on-call policies;
 3. record keeping and reporting;
 4. confidentiality and privacy of Protected Health Information (PHI);
 5. patient's rights;
 6. advance directives;
 7. written clinical policies and procedures;
 8. training for special populations such as pediatrics, ventilator care, tracheostomy care, wound, infusion care;
 9. professional boundaries;
 10. supervisory visit requirements to include new and experienced personnel;
 11. criminal background checks;
 12. Occupational Safety and Health Administration (OSHA) requirements, safety, infection control;
 13. orientation to equipment;
 14. cardiopulmonary resuscitation training and documentation;
 15. incident reporting;
 16. cultural diversity and ethnic issues; and
 17. translation policy.

Note: Documentation of all training and competency shall be retained in the personnel file of each licensed nurse and available to NC Medicaid upon request.

6.3 Provider Relationship to Beneficiary

NC Medicaid shall not cover PDN if:

- a. PDN is provided by the beneficiary's near relative (spouse, child, parent, grandparent, grandchild, or sibling, including corresponding step- and in-law relationships). They may be employed by the PDN service provider to work with other beneficiaries;
- b. The direct care nurse lives with the beneficiary in any capacity;
- c. The PDN service provider is owned by the beneficiary's near relative (spouse, child, parent, grandparent, grandchild, or sibling, including corresponding step- and in-law relationships); or
- d. PDN is provided by an individual who is legally responsible for the beneficiary.

6.4 Nurse Supervision Requirements

The PDN nurse supervisor shall have at least two (2) years of Intensive Care Unit, Coronary Care Unit, Neonatal Intensive Care Unit, Pediatric Intensive Care Unit or other experience in other critical care settings or two (2) years' home care experience with medically fragile beneficiaries or a combination of the previous. NC Medicaid prefers additional direct clinical supervisory experience.

6.5 Provider Certifications

None Apply

DRAFT

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

7.2 Documentation Requirements

7.2.1 Contents of Records

The PDN service provider is responsible for maintaining complete and accurate records of all care, treatment, and interventions that fully document the beneficiary's condition, nursing interventions, and treatment provided. The records shall contain:

- a. The date and time the skilled care was provided;
- b. All nursing interventions, to include time, activity, and beneficiary's response;
- c. Certification that all care was provided according to the attending physician's orders, the beneficiary's current individualized plan of care, and NC Medicaid approval;
- d. Signature of beneficiary or caregiver acknowledging time spent and services rendered. This signature shall be obtained daily;
- e. Indicate place of service, if other than residence (such as school, outings, travel to medical appointments);
- f. Use of medical supplies to support quantities delivered and used;
- g. Document to whom report was given and received from;
- h. indicate present and available caregivers;
- i. Document of caregiver education, competency and learning needs and progress toward teaching goals;
- j. Document safety issues and appropriate interventions;
- k. Coordination with other homecare services to ensure no duplication of services;
- l. Document other in-home services such as Respiratory Therapy, Therapy Services, Habilitation Aides, etc.;
- m. Document a medical update (such as a face-to-face encounter with physician/Non-Physician Provider) and submit to NC Medicaid with each reauthorization; and
- n. Document supervisory visits according to agency policy and licensure rules.

The PDN service provider(s) shall submit to NC Medicaid any requested documents that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

DRAFT

7.2.2 Termination of Operations

If an agency ceases operation, NC Medicaid shall be notified in writing where the records are stored. Clinical records shall be retained for six (6) years after the discharge of the beneficiary in accordance with the Department of Health and Human Services (DHHS) Provider Participation Agreement.

7.3 Verification of Eligibility

The PDN service provider is required to verify the beneficiary's NC Medicaid eligibility, NC Medicaid coverage category, private health insurance coverage, and living arrangement before initiating services and during delivery of PDN services.

7.4 Qualified Family and Other Designated Caregivers

7.4.1 Primary, Trained Informal Caregivers

The beneficiary shall have at least one (1) primary, trained informal caregiver. If there is no trained, informal caregiver to assume this role, PDN shall not be approved. It is recommended that there also be a secondary/back-up, trained informal caregiver for instances of primary informal caregiver unavailability due to illness or emergency and for occasional respite for the primary, trained informal caregiver. Both informal caregivers shall be trained and available to provide care in the home during the absence of the PDN nurse and as required by the beneficiary's medical status.

7.4.2 Training

As part of the PDN service, the PDN service provider shall provide and document training and educational needs of the beneficiary (when applicable), family members, and designated caregivers in accordance with the beneficiary's plan of care. In particular, training provided by the PDN service provider and by the hospital prior to a beneficiary's beginning PDN services, should be documented.

7.4.3 Documenting Competency

Family members and other designated caregivers shall demonstrate competency in providing the care that the beneficiary requires when the PDN nurse is not present. The PDN service provider is responsible for documenting family members and other designated caregivers who have demonstrated competency in providing the care required by the beneficiary. Documentation of discharge teaching provided by a hospital may be part of documenting competency.

7.4.4 Emergency Plan of Action

An emergency plan of action shall be developed, and all family members and caregivers shall know the procedures to take if the beneficiary requires emergency medical care.

7.4.5 Evaluation of Health and Safety

Prior to initiating services and with continuation of PDN services, the PDN service provider is responsible for evaluating the family and home environment in terms of the health, safety, and welfare of the beneficiary and PDN nursing staff, consistent with the agency's policies and licensure requirements.

DRAFT

7.5 Patient Self Determination Act

The Patient Self Determination Act of 1990, Sections 4206 and 4751 of the Omnibus Budget Reconciliation Act of 1990, P.L.101-508 requires that Medicaid-certified hospitals and other health care providers and organizations, give patients information about their right to make their own health decisions, including the right to accept or refuse medical treatment. Providers shall comply with these guidelines. *NCTracks Provider Claims and Billing Assistance Guide*:

<https://www.nctracks.nc.gov/content/public/providers/providermanuals.html>

7.6 Marketing Prohibition

Agencies providing PDN services through NC Medicaid are prohibited from offering gifts or services of any kind to entice beneficiaries or their informal or formal caregivers to choose said PDN service provider as their PDN service provider, or to entice beneficiaries or their informal or formal caregivers to change from their current PDN service provider.

DRAFT

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1988 Revision

Information:

Date	Section Revised	Change
12/01/2012	All sections and attachment(s)	Initial promulgation of coverage from a manual.
12/01/2012	All sections and attachment(s)	Technical changes to merge Medicaid and NCHC current coverage into one policy.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
02/01/2016	Subsection 6.2.1.b	Removed statement, "All current PDN providers shall be fully accredited within 18 months of the effective date of this policy."
03/01/2017	All Sections and Attachments	Changed name and number to "3G-1 Private Duty Nursing for Beneficiaries Age 21 and Older"
03/01/2017	All Sections and Attachments	Portions of the policy pertaining to beneficiaries under 21 years of age were removed.
03/01/2017	Subsection 5.2.2.3	Added provisional prior approvals for Initial PDN Referrals
03/01/2017	Various Sections	Changed the certification period from 60 days to 90 days.
03/01/2017	Various Sections	Removed the experience requirement for PDN nurses
03/01/2017	Various Sections	Expand the expertise areas for PDN Nursing Supervisors.
05/12/2017	All Sections and Attachments	Policy posted 05/12/2017 with an Amended Date of 03/01/2017
11/01/2017	All Sections and Attachment (s)	Grammar, formatting, and hyperlink updates and corrections
11/01/2017	All Sections and Attachment (s)	Increased prior authorization (PA) certification period from 60 calendar days to 6 months
11/01/2017	Sections 5.2.3.3, 5.2.4.1, 5.2.4.2	Removed text in 5.2.3.3 Emergency Changes, 5.2.4.1 Notification of Termination, and 5.2.4.2 Notification of Reduction, as it was duplicative of already posted Due Process Policies and Procedures.
11/01/2017	All Sections and Attachment (s)	Added 'physician' to clarify need for physician signed CMS_485 for PA approval.
11/01/2017	Section 3.4 and 4.2.2	Removed information about CAP/C beneficiaries – transition is complete. Moved information about hours for other formal support programs to Section 4.2.2
11/01/2017	Section 5.2.2.5	Removed 'specific' and 'range of hours not acceptable'. Per 42CFR 409.43 Plan of Care Requirements, the frequency of visits may be stated as a specific range to ensure the most appropriate level of care is provided.

DRAFT

11/21/2017	All Sections and Attachments	Corrected an error in the document style that was causing some subsection headings to display incorrectly. No change to content or amended date.
09/01/2021	Section 5.2.6.5	Added the following language: Medical supplies are covered as per the criteria for coverage of medical supplies and use of the miscellaneous procedure code for medical supplies defined in clinical coverage policies 3A, <i>Home Health Services</i> and 5A, <i>Durable Medical Equipment</i> (available here: https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies/clinical-coverage-policy-index).
09/01/2021	Added beginning of Policy	Added the language “This clinical coverage policy has an effective date of November 15, 2020; however, until the end of the public health emergency, the temporary coverage and reimbursement flexibilities enabled by NC Medicaid through a series of COVID-19 Special Medicaid Bulletins will remain in effect.”
09/01/2021	Section 1.0	Removed reference to services in a hospital or skilled nursing facility. Removed “only” from place of service.
09/01/2021	Section 1.1.1	Expanded skilled nursing definition. Added Administrative code for RN, LPN and In-Home Aide scope of practice.
09/01/2021	Section 1.1.5	Clarified definition.
09/01/2021	Section 1.1.7	Clarified primary caregiver definition and added secondary caregiver definition.
09/01/2021	Section 2.1.2	Updated terminology to include managed care.
09/01/2021	Section 2.2.1	Updated EPSDT URL to direct to the EPSDT provider page as referenced.
09/01/2021	Section 3.2.2	Clarified caregiver requirement.
09/01/2021	Section 3.3.1	Added additional criteria 9 and 10 to be more inclusive.
09/01/2021	Section 3.3.2	Removed case specific factors.
09/01/2021	Section 3.4	Updated approval table.
09/01/2021	Section 3.4.1	Increased duration to a maximum of 6 calendar weeks and expanded family emergency definition.
09/01/2021	Section 3.4.2	Added process to allow 14 days per calendar year of physician-ordered non-medical leave that cannot exceed the current approved hours. Clarified therapeutic leave definition to include vacation.
09/01/2021	Section 5.2.2.1	Clarified process.
09/01/2021	Section 5.2.2.2	Clarified and streamlined process.
09/01/2021	Section 5.2.2.3	Clarified and streamlined process. Clarified CMS 485 submission timeframe.
09/01/2021	Section 5.2.2.4	Clarified as per Centers for Medicare and Medicaid guidelines and clarified CMS 485 submission requirements. Clarified RN-verbal CMS 485 submission

DRAFT

		as an acceptable document.
09/01/2021	Section 5.2.2.5	Clarified and streamlined the process. Clarified RN-verbal CMS 485 submission as an acceptable document.
09/01/2021	Section 5.2.2.5	Clarified notification process.
09/01/2021	Section 5.2.2.6	Clarified re-evaluation process and increased to reporting within 5 business days, which is consistent with reporting other changes within the policy.
09/01/2021	Section 5.2.3	Clarified process.
09/01/2021	Section 5.2.3.1	Clarified section name.
09/01/2021	Section 5.2.3.2	Clarified emergency change process and increased to reporting within 5 business days, which is consistent with reporting other changes within the policy.
09/01/2021	Section 5.2.4.2	Clarified notification process.
09/01/2021	Section 5.2.5	Clarified notification process.
09/01/2021	Section 5.2.5.2	Clarified and streamlined the process. Added provisional approval timeframe.
09/01/2021	Section 5.2.5.2.1	Streamlined process and added provisional review.
09/01/2021	Section 5.2.5.2.2	Streamlined process and added continuation review.
09/01/2021	Section 5.2.5.3	Streamlined process and added shared case process. Removed Discharge Summary and Approval process.
09/01/2021	Section 5.2.5.3.1	Streamlined and Added Shared Provisional Review process.
09/01/2021	Section 5.2.5.3.2	Streamlined and Added Shared Continuation Review process.
09/01/2021	Section 5.2.5.3.3	Streamlined process and added Re-distribution of Shared Hours process.
09/01/2021	Section 5.2.6.1	Increased to within 5 business days which is consistent with reporting other changes within the policy.
09/01/2021	Section 5.2.6.2	Removed reference to Part D.
09/01/2021	Section 5.2.6.4	Clarified PDN provider role in Home Health nursing tasks.
09/01/2021	Section 5.3.4	Clarified notification timeframe to within 10 business days.
09/01/2021	Section 6.3	Clarified to provide additional details as to who may be employed to provide services.
09/01/2021	Section 7.2.2	Clarified as per Department of Health and Human Services Provider Participation Agreement.
09/01/2021	Section 7.4.1	Added language to clarify caregiver role.
09/01/2021	Section 7.6	Added language to clarify informal vs formal caregiver role in marketing practices.
09/01/2021	Section 8.0	Added Attachment B: PDN Forms with link to webpage.
09/01/2021	All sections	Updated all policy links.
09/01/2021	All Sections and Attachments	Updated “DMA” to “NC Medicaid,” “primary physician” to “attending physician,” as applicable, “provider” to “PDN service provider,” and “eligibility” to “NC Medicaid eligibility.”

DRAFT

00/00/0000	Section 2.0 Eligibility Requirements: 2.1.2 (a)	Removed: Medicaid for Pregnant Women (MPW): Pregnant women may be eligible to apply for PDN services if the services are medically necessary for a pregnancy-related condition.
------------	----------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

DRAFT

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

HCPCS Code(s)	Program Description
T1000	PDN Nursing Services

Note: Medical supplies are billed using HCPCS supply codes as indicated on the Home Health Fee Schedule. The Home Health Fee Schedule lists the covered supplies. Refer to NC Medicaid’s Web site at <https://medicaid.ncdhhs.gov/>.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

Modifiers are required for billing PDN nursing services as follows: TD for RN care and TE for LPN care.

DRAFT

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

1. PDN Services

PDN services are billed in 15-minute units and shall not exceed the NC Medicaid authorized number of PDN units per week. The qualifications of the nurse shall be specified.

2. Medical Supplies

Medical supplies are paid by item and quantity supplied and according to the Medicaid Home Health Fee Schedule. Refer to **Subsection 5.2.6.5** for coverage criteria.

F. Place of Service

PDN services are provided in the beneficiary's private primary residence. Refer to **Subsection 4.2**

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at <http://dma.ncdhhs.gov/document/state-plan-under-title-xix-social-security-act-medical-assistanceprogram>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

Reimbursement is based on the NC Medicaid Home Health and Private Duty Maximum Rate Schedule, available at: <https://medicaid.ncdhhs.gov/>

Program Integrity

The Office of Compliance and Program Integrity (OCPI) section of NC Medicaid investigates PDN services provided without authorization. PDN service providers that render services that are not medically necessary or not performed as documented on the CMS 485 (Home Health Certification and Plan of Care Form) are referred to Medicaid's OCPI unit for evaluation and potential recoupment of reimbursement.

Licensed nurses who falsify medical records in an effort to qualify a beneficiary for PDN services are referred to the N.C. Board of Nursing or the appropriate North Carolina Health Care Personnel Registry (DHSR, the N.N. Board of Nursing or both).

Unit Limitations

The following limits apply:

Billed time cannot exceed the number of units per week authorized by NC Medicaid.

DRAFT

Attachment B: PDN Forms

Provider(s) shall access required PDN forms via the PDN webpage:

<https://medicaid.ncdhhs.gov/providers/programs-and-services/long-term-care/private-duty-nursing-pdn> .