Molina Clinical Policy
Noninvasive Positive Pressure Ventilation: Policy No. 275

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Noninvasive positive pressure ventilation (NIPPV, NPPV) refers to the delivery of mechanical positive pressure ventilatory support via a noninvasive interface (nasal mask, facemask, or nasal plugs), as opposed to an invasive interface (endotracheal tube or tracheostomy). The use of NIPPV has increased in the acute care hospital setting, the long-term care hospital, and the home for the management of patients with both acute respiratory failure and chronic respiratory failure requiring prolonged mechanical ventilation. Home NIPPV has mainly been investigated for use in patients with obstructive lung disease, neuromuscular disease, obesity hypoventilation syndrome (OHS), and restrictive chest wall disease.

Both bilevel positive airway pressure (BiPAP) devices and noninvasive ventilators (NIVs) can deliver noninvasive positive pressure ventilation, however their technical features may vary considerably. Key areas of variability include mode of ventilation (pressure targeted versus volume targeted), monitoring capability, safety and alarm systems, and presence of a flow sensor. Due to advancements in technology, it is becoming increasingly more difficult to clearly discern one device category from the other. Many home ventilators are multi-mode ventilators, capable of providing multiple modes of ventilation including pressure control, volume control, assist/control, synchronized intermittent mandatory ventilation (SIMV), bilevel positive pressure (BiPAP, BPAP) or continuous positive airway pressure (CPAP); and are capable of supporting patients invasively or noninvasively.

Considering the user's needs when selecting an appropriate positive pressure ventilation assist device is essential. For situations in which there is a risk of acute respiratory failure, hypoventilation, or apnea; the NIV will sound an alarm where the home BiPAP unit may not. NIVs are also generally equipped with batteries to serve as a back-up source of power for several or more hours should the primary power source fail. Additionally, NIVs have the capability of delivering ventilation based on volume and precise levels of oxygen needed by more complex patients.

COVERAGE POLICY

This policy does not address the use of other respiratory assist devices including BiPAP or CPAP device. Please see Milliman MCG for criteria. These devices are considered first line treatment for many conditions and should be tried before following the criteria outlined below whenever appropriate.

Noninvasive positive pressure ventilation (NPPV) with a ventilator approved by the FDA for home use **may be considered medically necessary** when the following criteria are met:

1. **Diagnosis of chronic respiratory failure due to progressive neuromuscular disease** (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord injuries, spinal muscular atrophy, diaphragmatic paralysis, myasthenia gravis, amyotrophic lateral sclerosis) or severe chest wall disorder (e.g., kyphoscoliosis, asphyxiating thoracic dystrophy); **AND**

2. **Mechanical ventilation required** due to respiratory insufficiency with **one or more** of the following:
   a. Arterial O2 saturation < 88% for 5 consecutive minutes during nocturnal oximetry
   b. Arterial PCO2 ≥ 45 mm Hg (6.0 kPa)
   c. Maximal inspiratory pressures < 60 cm/H2O
   d. Forced Vital Capacity (FVC) < 50% predicted

OR

3. **Diagnosis of chronic obstructive pulmonary disease (COPD)** and **one or more** of the following: [ONE]
   a. Palliative care in patient with end-stage disease and advance directive stating no desire for intubation; **OR**
   b. Chronic hypercapnia and **ALL** of the following:
      - Patient has documented failure of BIPAP (including both simple and advanced modes, such as AVAPS and iVAPS) to improve hypercapnia and/or oxygen saturation level; **AND**
      - Prescription for NIV should be written by a pulmonologist (or arrangements have been made for pulmonary follow-up within 3 months); **AND**

OR

4. **Diagnosis of Obesity Hypoventilation Syndrome (OHS)** and **ALL** of the following:
   a. BMI greater than or equal to 30 kg/m^2
   b. Daytime hypercapnia with PaCO2 greater than 45 mm Hg (6.0 kPa) without other etiology (e.g., kyphoscoliosis, lung parenchymal disease, myopathy, severe hypothyroidism)
   c. Sleep-disordered breathing or hypoventilation on polysomnography, as indicated by **one or more** of the following:
      - Apnea-hypopnea index of 5 or greater
      - Increase in PaCO2 during sleep by more than 10 mm Hg (1.3 kPa) above value while awake
      - Significant oxygen desaturation (e.g., O2 < 90%) not explained by obstructive apneas or hypopneas
      - TSH level does not demonstrate hypothyroidism
   d. Failure to improve arterial oxygen saturations and/or hypercapnia on CPAP or BiPAP devices
   e. Diagnosis and prescription for the device must be made by a pulmonologist or other relevant specialty physician.
   f. The NIPPV device is FDA approved for the clinical indications
   g. None of the following conditions are present:
      - Alteration in level of consciousness (i.e., alert and oriented)
      - Anatomic abnormality that precludes mask fitting (facial or neurological surgery, trauma, or deformity)
      - High risk for aspiration (excessive secretions, impaired cough, or inability of mechanically assisted cough to clear secretions)
      - Swallowing disorder
      - Inability to cooperate/protect airway
      - Upper airway obstruction

OR

5. **BPAP or CPAP device is not appropriate** when the Member meets **one or more** of the criteria below:
   a. Chronic respiratory insufficiency fails to improve with a bilevel respiratory assistance device (both simple and advanced modes)
   b. Settings or functionality required by patient is not available with a bilevel respiratory assistance device (both simple and advanced modes), as indicated by **one or more** of the following:
      - Alarms required by patient are not available on bilevel positive pressure respiratory assistance device
      - Daytime ventilation using mouthpiece required
      - Pressure range delivered by device (e.g., expiratory or inspiratory pressure) not appropriate for patient
      - Volume-assured pressure support or volume control mode is required (e.g., OHS)
   c. Ventilated patient requires cough assistance via volume ventilator's breath stacking capability
   d. Ventilation is required 24 hours a day

** Per coding guidelines, when BiPAP is documented and performed CPT 94660 (Continuous positive airway pressure ventilation (CPAP), initiation and management) is the appropriate code as BiPAP is a noninvasive mechanical ventilation that includes (CPAP) and pressure support ventilation

Continuation of Therapy

For establishment of **continued medical necessity** beyond 3 months, the medical records should document that the member has been compliantly using the device (an average of 4 hours per 24-hour period, and that the member is benefiting from its use. Approval of continuation of use also requires that indications for the initial approval above are still be met. The following is required for continuation review:

- Compliance with use is reported every three months including documentation of compliant use of the device monitor for an average of 4 or more hours per 24 hours (includes documentation from the requesting provider stating continued benefit of use).
- Initial rental authorization of the device is for 90 days. Compliance is confirmed using a smartcard or other similar report. This verification should be completed within the first 90 days of therapy to assist with long-term rental authorizations. (Note: Smartcards are an important part of NIV management and are not separately reimbursable).
- Documentation for a specialist referral.
- Documentation of symptomatic improvement with the use of a ventilator.
- Documentation of a sleep study if treatment is for severe obstructive sleep apnea (OSA).
- Documentation of pulmonary function tests (PFTs) +/- arterial blood gases (ABG) if treatment is for severe COPD or OHS.

Limitations and Exclusions

Home non-invasive positive pressure ventilators are excluded and not medically necessary for the treatment of **ANY** of the following conditions or scenarios:

1. Obstructive sleep apnea as the clinical outcomes have not been shown to be superior to other standard treatments (e.g., CPAP, BiPAP).
2. Other conditions/diseases including but not limited to cystic fibrosis due to insufficient evidence in the peer reviewed medical publications.
3. Chronic stable COPD without hypercapnia, and central sleep apnea of heart failure.
4. Acute respiratory distress syndrome (ARDS).
5. Ventilation is required continuously (24 hours/day).

Due to limited evidence-based support, contraindications include, but are not limited to:

- Altered mental status or confusion
- Drowsiness or loss of consciousness
- Excessive mucus production or respiratory secretion
- Facial trauma or other abnormalities
- Hemodynamic instability
- Nausea and/or vomiting
- Respiratory arrest

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The peer reviewed published literature is sufficient to confirm improved outcomes of NIPPV in patients with chronic respiratory failure due to progressive neuromuscular disorders (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord diseases, diaphragmatic paralysis, myasthenia gravis, amyotrophic lateral sclerosis). There are meta-analysis, systematic reviews and randomized controlled trials that have determined positive clinical effects of non-invasive ventilation and validate clinical net health outcomes of home NIPPV. A systematic review conducted by Annane et al. (2014) studied quasi-randomized or randomized controlled trials of participants of all ages with neuromuscular or chest wall disorder-related stable chronic hypoventilation of all degrees of severity, receiving any type and any mode of long-term nocturnal mechanical ventilation. The assessment included 10 trials with a total of 173 participants. Roughly half of the trials were at low risk of selection, attrition or reporting bias, and almost all were at high risk of performance and detection bias. Four trials reported mortality data in the long term. The authors concluded that Current evidence on the therapeutic benefit of mechanical ventilation is of very low quality, but is consistent, suggesting alleviation of the symptoms of chronic hypoventilation in the short term. In four small studies, survival was prolonged and unplanned hospitalization was reduced, mainly in participants with motor neuron diseases. Except for motor neuron disease and Duchenne muscular dystrophy, for which the natural history supports the survival benefit of mechanical ventilation against no ventilation, further larger randomized trials should assess the long-term benefit of different types and modes of nocturnal mechanical ventilation on quality of life, morbidity and mortality, and its cost-benefit ratio in neuromuscular and chest wall diseases.

For restrictive disorders of the chest wall (e.g., kyphoscoliosis, fibrothorax, asphyxiating thoracic dystrophy), available evidence demonstrates at least moderate net benefit. A systematic review (Hannan et al., 2014) examined the effect of NOPPV on patient reported outcomes and survival for individuals with or at risk for chronic respiratory failure. Eighteen studies were included, and overall study quality was weak. For restrictive thoracic disease, measures of dyspnea, sleep quality, physical function and health, mental and emotional health and social function improved.

The peer reviewed published medical literature is insufficient to confirm improved outcomes of NIPPV in patients with cystic fibrosis and obstructive sleep apnea. Further investigation is needed with larger populations to determine appropriate candidates for NIPPV and validate long-term, predictable outcomes. Studies thus far have yielded mixed results due to methodological issues and problems with compliance. There is a need for long-term randomized controlled trials which are adequately designed to determine the clinical effects of non-invasive ventilation and explore potential interventions that can improve compliance, decrease adverse events associated with non-compliance, and validate clinical net health outcomes of home NIPPV (Moran et al., 2017).

For OHS, noninvasive bilevel positive pressure respiratory assistance devices (BPAP) may not supply sufficient pressure to adequately ventilate some patients with severe restrictive lung disease due to obesity. These patients may require support from a noninvasive home ventilator capable of delivering volume driven support. A multicenter, open-label, randomized controlled trial (Masa et al., 2019) compared CPAP with NIV in 2015 patients with OHS and apnea hypopnea index (AHI) of 30 or greater. At the median follow up was 5.44 years, the mean hospitalization days per patient-year were 1.63 in the CPAP group and 1.44 in the NIV group. Adverse events were similar in both groups. Therapy complexity was lower in the CPAP group. The authors concluded that given the two methods offer similar long-term effectiveness, CPAP may be the preferred first-line treatment modality given its lower complexity. A review by Selim et al. (2018) notes that approximately 60% of patients with OHS will respond to CPAP therapy, while the remainder generally respond to BPAP therapy.

A multidisciplinary panel conducted a full systematic review to address five clinical questions in development of the American Thoracic Society (ATS) *Clinical Practice Guideline for the Evaluation and Management of Obesity Hypoventilation Syndrome* (Mokhlesi et al., 2019). The guideline provides the following recommendations:

- We suggest clinicians use a serum bicarbonate level <27 mmol/L to exclude the diagnosis of OHS in obese patients with sleep-disordered breathing when suspicion for OHS is not very high (<20%) but to measure arterial blood gases in patients strongly suspected of having OHS
- We suggest stable ambulatory patients with OHS receive positive airway pressure (PAP)
- We suggest continuous positive airway pressure (CPAP) rather than noninvasive ventilation be offered as the first-line treatment to stable ambulatory patients with OHS and coexistent severe obstructive sleep apnea

- We suggest patients hospitalized with respiratory failure and suspected of having OHS be discharged with noninvasive ventilation until they undergo outpatient diagnostic procedures and PAP titration in the sleep laboratory (ideally within 2–3 months)
- We suggest nocturnal home therapy with NPPV be offered if CPAP/BiPAP fail to correct hypoventilation
- We suggest patients with OHS use weight-loss interventions that produce sustained weight loss of 25% to 30% of body weight to achieve resolution of OHS (which is more likely to be obtained with bariatric surgery).

The peer reviewed published medical literature is sufficient and demonstrates at least a moderate net benefit of NIPPV in patients with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD). A multicenter randomized controlled trial of 195 patients with stable chronic obstructive pulmonary disease who were classified as having hypercapnic Global Initiative for Chronic Obstructive Lung Disease stage IV disease found, at 12-month follow-up, that the use of noninvasive positive pressure ventilation was associated with lower mortality as compared with usual care (12% and 33%, respectively) (Köhnlein et al., 2014). A randomized controlled trial of 116 chronic obstructive pulmonary disease assigned patients with persistent hypercapnia and hypoxemia to home oxygen with or without noninvasive positive pressure ventilation for a 12-month period. Patients using noninvasive ventilation experienced longer time to readmission or death (i.e., median 4.3 months vs 1.4 months in the oxygen alone arm) (Murphy et al., 2017). A randomized trial of nocturnal NIV (known as the Assisted Ventilation in Chronic Airflow Limitation study or AVCAL) was performed in 144 patients with severe COPD and moderate hypercapnia (PaCO2 >46 mmHg). The effects on survival, lung function, and quality of life of NIV plus long-term oxygen therapy (LTOT) were compared with LTOT alone. NIV plus LTOT improved sleep quality and initial nocturnal hypercapnia, with fair compliance to NIV therapy (mean nightly use [standard deviation (SD)], 4.5 [3.2] hours/night). After a mean follow-up of 2.2 years, the NIV group had an improved survival out to 36 months, but thereafter the survival curves converged. The forced expiratory volume in one second (FEV1) and PaCO2 at 6 and 12 months were not different between the groups. Despite improved initial survival and sleep quality, quality of life was actually lower with NIV (McEvoy et al., 2009).

Raveling et al. (2021) conducted an updated systematic review to assess the effects of chronic non-invasive ventilation at home in people with COPD. The authors included randomised controlled trials (RCTs) comparing chronic nocturnal NIV in addition to standard care versus standard care alone. Studies investigating people initiated on NIV in a stable phase and studies investigating NIV commenced after a severe COPD exacerbation were reported and analyzed separately. The primary outcomes evaluated were arterial blood gases, health-related quality of life (HRQL), exercise capacity (stable COPD) and admission-free survival (post-exacerbation COPD). Secondary outcomes for both populations included lung function, COPD exacerbations and admissions, and all-cause mortality. A total of 21 studies (including 778 people with stable COPD and 364 people with post-exacerbation COPD) met inclusion criteria. Results showed that in all people with COPD who had raised levels of carbon dioxide, chronic NIV for 3- and 12- months improved blood gases. In stable COPD, chronic NIV also might have improved quality of life, and survival seemed to be better compared to people who were treated with standard care only. There was no relevant benefit of NIV on exercise capacity. People using chronic NIV after a COPD admission experienced less benefit; carbon dioxide levels decreased, the time to the next hospital admission might have been longer when treated with NIV but quality of life and survival were not affected by chronic NIV. Confidence in the certainty was good in relation to blood gases; for other outcomes, certainty of the evidence is moderate to very low due to participants and researchers not being blinded.

National and Specialty Organizations

An **American Thoracic Society (ATS)** Clinical Practice Guideline on Long-Term Noninvasive Ventilation in Chronic Stable Hypercapnic COPD (Macrea et al., 2020) provides the following five evidence-based recommendations:

- We suggest the use of nocturnal NIV in addition to usual care for patients with chronic stable hypercapnic COPD (conditional recommendation, moderate certainty)
- We suggest that patients with chronic stable hypercapnic COPD undergo screening for obstructive sleep apnea before initiation of long-term NIV (conditional recommendation, very low certainty)
- We suggest not initiating long-term NIV during an admission for acute-on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIV at 2–4 weeks after resolution (conditional recommendation, low certainty); 4) we suggest not using an in-laboratory overnight polysomnogram to titrate NIV in patients with chronic stable hypercapnic COPD who are initiating NIV (conditional recommendation, very low certainty)
- We suggest NIV with targeted normalization of PaCO2 in patients with hypercapnic COPD on long-term NIV (conditional recommendation, low certainty).

According to the **Global Initiative for Chronic Obstructive Lung Disease (GOLD)** 2022 Guidelines (2021), "Whether to use NPPV chronically at home to treat patients with acute on chronic respiratory failure following hospitalization remains undetermined and outcome may be affected by persistent hypercapnia (Kolodziej et al., 2007)." NPPV may improve hospital-free survival for select patients, particularly in those with persistent daytime hypercapnia ($PaCO_2 \geq 52$mmHg). When indicated, NIPPV should be implemented and monitored by specialists familiar with the equipment and appropriate plan of care.

The **National Institute for Health and Clinical Excellence (NICE)** guideline NG115 (2019) on COPD diagnosis and management states, "Refer people who are adequately treated but have chronic hypercapnic respiratory failure and have needed assisted ventilation (whether invasive or non-invasive) during an exacerbation, or who are hypercapnic or acidotic on long-term oxygen therapy, to a specialist center for consideration of long-term non-invasive ventilation."

A technology assessment prepared for the **Agency for Healthcare Research and Quality** by the Mayo Clinic Evidence-based Practice Center (Wilson et al., 2020) evaluated the use of NIPPV in adult patients with chronic respiratory failure due to a variety of primary causes including COPD, thoracic restrictive disorders, neuromuscular disease, and OHS. Randomized and comparative nonrandomized studies that enrolled adults with chronic respiratory failure who used NIPPV for ≥ 1 month at home using a home mechanical ventilator (HMV), bi-level positive airway pressure (BPAP) device, or continuous positive airway pressure (CPAP) device were selected for inclusion, resulting in a total of 68 studies evaluating 53,733 patients. Study limitations include the inability to fully account for the type of device used, equipment settings, and other respiratory services provided. The following conclusions were made:

- In patients with COPD, home BPAP (compared to no device) was associated with lower mortality, decreased need for intubations, fewer patients with hospital admissions but no difference in the total number of hospital admissions or quality of life.
- In patients with stable COPD, NIPPV compared with no device was associated with no difference in the total number of hospital admissions.
- In patients with COPD and recent exacerbation, NIPPV compared with no device was associated with no difference in mortality (OR=0.66, 95% CI: 0.41 to 1.06), but was associated with fewer hospital admissions
- In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality.
- In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life.
- In patients with OHS, home HMV/BPAP (compared to no device) was associated with lower mortality.

The assessment also proposes that future research should look to determine which patient populations would benefit from an HMV versus BPAP device, when to optimally initiate treatment, comparative effectiveness of invasive versus noninvasive 24-hour ventilation, and the consequence of various features and device types on outcomes. The authors note that although randomized controlled trials may offer the highest level of evidence, enrolling patients requiring this type of treatment may not be ethical. Thus, other study designs, such as single arm interventional studies, may be the best available option.

The **European Respiratory Society** (2019) published a guideline titled *Long-Term Home (LTH) Non-Invasive Ventilation (NIV) for Management of COPD.* The following evidence-based recommendations were made regarding the clinical application of LTH-NIV in chronic hypercapnic COPD patients.

- Use of LTH-NIV in stable hypercapnic COPD.
- Use of LTH-NIV in COPD patients following a COPD exacerbation requiring acute NIV.
- Use of NIV settings targeting a reduction in carbon dioxide.
- Using fixed pressure support as first choice ventilator mode.

SUPPLEMENTAL INFORMATION

Chronic hypercapnia defined as $PaCO_2$ of 50 mm Hg (6.7 kPa).

CODING & BILLING INFORMATION

HCPCS Code

HCPCS	Description
E0466	Home ventilator, any type, used with noninvasive interface (e.g., mask, chest shell)
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy reviewed, updated Coverage Policy – included criteria for patients with COPD and for those when BPAP/CPAP is not indicated; added Continuation of Therapy section.
2/9/2022	Policy reviewed; updated Coverage Policy, Summary of Evidence, and Reference section.
2/8/2021	Policy reviewed, updated references.
4/23/2020	Policy reviewed, updated references.
9/18/2019	Policy reviewed, Summary of Evidence and Reference section updated.
7/16/2018	Policy reviewed; updated Coverage Policy, Summary of Evidence, and Reference section. Added medically necessary criteria for the diagnosis of COPD and chronic restrictive hypoventilation syndrome related to obesity.
12/13/2017	Policy reviewed, no changes to criteria, updated references.
5/23/2016	New policy.

REFERENCES

Government Agencies

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2. Wilson M, Wang Z, Dobler CC, et al. Noninvasive positive pressure ventilation in the home (with addendum). Technology Assessment Project ID: PULT0717. Rockville (MD): Agency for Healthcare Research and Quality (US); Apr 2, 2020. Available from NIH.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on October 11, 2022 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Pulmonary Disease, Critical Care.
2. Dane Street Peer Review. Policy reviewed on December 12, 2022 by a Dane Street practicing, board-certified physician in the area of Pulmonary Disease.
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