Please return all correspondence to:

«TableStart:PATIENTINFO»«Facility_Description»

NPI: «Facility_NPI»
Tax ID: «Facility_Tax_ID»
PTAN: «PTAN»
«TableEnd:PATIENTINFO»
April 9, 2020
«TableStart:PAYERINFO»
«PAY_Payer_Address1»
«PAY_Payer_City», «PAY_Payer_State» «PAY_Payer_Zip_Code»
«TableEnd:PAYERINFO»
«TableStart:PATIENTINFO»«Salutation_Recipient»:

This is a request for «Appeal_Description» on «PAT_Full_Name»'s denied claim for inpatient services at «Facility». The following is a summary of the denial from «Prior_Reviewing_Agency», as well as substantiation of the medical necessity that supports the need for services as provided and billed.

Beneficiary Name	«PAT_Full_Name»
Member ID or HIC Number	«MEMBER_ID»
Claim Dates of Service	«Svc_From» - «Svc_To»
Reason(s) for Denial	Allegation: Services provided not reasonable or medically necessary
Principal Diagnosis	
Comorbidities/Complicating Factors	
Procedures	
Social Factors	

Justification for Appeal

«PAT_Full_Name» *was a [blind, wheelchair bound, developmentally delayed, brain-injured,] ___ year-old [disabled/widowed] [lady/gentleman] who lived [alone, in a NH, ALF, etc.] with a medical history as outlined above and a family history of _____ [list pertinent family history, if applicable]. Of note,* «PAT_Full_Name» *routinely took [# of medications & any allergies with allergic response if severe].*

«PAT_Full_Name» *presented to the hospital Emergency Department via [ambulance (if applicable)] after experiencing [description of acute symptoms. Avoid the word complaining]. Continue with the patient's presenting signs and symptoms, abnormal findings on physical exam, abnormal test results, and treatments started in the ED. Include the ED physician's presumed and/or admitting diagnoses (if documented). Include presenting date and time and admission and/(or transfer from ED to hospital bed) date and time.* «PAT_Full_Name» *was [admitted as an inpatient/initially placed in observation] on the [Telemetry/Medical-Surgical/Observation] unit.*

Continue to tell a compelling true story of the relevant hospital course - this patient's experience from just prior to presentation to post discharge plan, and how all the factors listed above tie together to support that the patient was severely ill enough, at a high risk of death or further disability, required intensive medical care, services, testing, and monitoring, to justify the physician's inpatient decision and the assumption that the patient would need to stay at least 2 midnights in the hospital. Include the attending physician's plan of care when it supports the need for hospital care. Include the specialty/interdisciplinary consultations ordered along with their findings and recommendations.

Cite all relevant abnormal findings. Include the tags of (H), (L), or (C) after the findings with the normal range for the specific facility's laboratry included in straight brackets. For example, Potassium 6.0 (C) [3.5-5.5]. Avoid using words like some, a little, minor, etc., while incorporating words like significant, severe, abnormal, elevated, decreased, as long as that is supported in the medical record. For example, if the ECHO states "mild pulmonary hypertension" just write pulmonary hypertension. If the patient has severe aortic stenosis, write severe aortic stenosis.

Note if the patient received > 2 midnights of hospital care counting from the time hospital care begins in the ED, OR, treatment area, or in the bed for a direct admit until the patient is wheeled out the door. (Hospital care starts after registration and intial triaging activities.) In other words, pull together and connect all clinical evidence available in the medical record to justify severity of illness and medically necessary hospital care expected to span two midnights.

If the patient did not receive >2 midnights of hospital care as described above, indicate what documentation in the medical record supports the unforeseen circumstance that resulted in a shorter beneficiary stay than the physician's expectation such as death, transfer, departure against medical advice (AMA), unforeseen recovery or election of hospice care.

Write your appeal justification as a narrative of both the art and science of medicine; using full sentences, with correct grammar and spelling, and making it as interesting to the reader as possible. This helps the ALJ (who is not a clinician) "picture" this patient's crisis situation and justifies the attending physician's admission decision to admit to an inpatient level of care.

Justification of Treatment and Setting by CMS Guidelines under the FY 2014 Hospital IPPS Final Rule CMS-1599-F

For cases with Admission Dates on or after 1/1/2015

	ADMISSION ORDER: A physician order is present in the medical record and supported by the physician admission and progress notes, and signed prior to discharge by a practitioner familiar with the case and authorized by the hospital to admit inpatients. Federal Register /Vol. 79, No. 217 /Monday, November 10, 2014 /Rules and Regulations; XVI. Revision of the Requirements for Physician Certification of Hospital Inpatient Services Other Than Psychiatric Inpatient Services and 42 CFR 412.3
	Please cite title of document and page numbers that support this guideline (if applicable).
	2 MIDNIGHT EXPECTATION: There is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required medically necessary care spanning at least 2 midnights. Federal Register / Vol. 78, No. 160 / Monday, August 19, 2013 / Rules and Regulations. Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A.
	Please cite title of document and page numbers that support this guideline (if applicable).
	DECISION TO ADMIT: The admission decision is supported through documention by the admitting provider of consideration of complex medical factors such as history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event and consideration of various other factors, including the beneficiary's age, disease processes, and the potential impact of sending the beneficiary home. FREQUENTLY ASKED QUESTIONS, 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013
	Please cite title of document and page numbers that support this guideline (if applicable).

Sources

2013 CMS Fact Sheet: CMS Finalizes FY 2014 Policy and Payment Changes for Inpatient Stays in Acute-Care And Long-Term Care Hospitals; August 2, 1013

Admission and Medical Review Criteria for Inpatient Services. The final rule modifies and clarifies CMS's longstanding policy on how Medicare contractors review inpatient hospital admissions for payment purposes. Under this final rule, **in addition to services designated as inpatient-only, surgical procedures, diagnostic tests and other treatments are generally appropriate for inpatient hospital admission and payment under Medicare Part A when the physician (1) expects the beneficiary to require a stay that crosses at least two midnights and (2) admits the beneficiary to the hospital based upon that expectation.** This policy responds to both hospital calls for more guidance about when a beneficiary is appropriately treated—and paid by Medicare—as an inpatient, and beneficiaries' concerns about increasingly long stays as outpatients due to hospitals' uncertainties about payment.

The final rule specifies that the timeframe used in determining the expectation of a stay surpassing two midnights begins when the beneficiary starts receiving services in the hospital. This includes outpatient observation services or services in an emergency department, operating room or other treatment area. While the final rule emphasizes that the time a beneficiary spends as an outpatient before the formal inpatient admission order is not inpatient time, the physician—and the Medicare review contractor—may consider this period when determining if it is reasonable and generally appropriate to expect the patient to stay in the hospital at least two midnights as part of an admission decision. **Documentation in the medical record must support a reasonable expectation of the need for the beneficiary to require a medically necessary stay lasting at least two midnights.** If the inpatient admission lasts fewer than two midnights due to an unforeseen circumstance this also must be clearly documented in the medical record.

FREQUENTLY ASKED QUESTIONS
2 Midnight Inpatient Admission Guidance &Patient
Status Reviews for Admissions on or after October 1, 2013

DOCUMENTING THE DECISION TO ADMIT

Q6: What documentation will review contractors expect physicians to provide to support that an expectation of a hospital stay spanning 2 or more midnights was reasonable?

A6: Review contactors' expectations for sufficient documentation will be rooted in good medical practice. Expected length of stay and the determination of the underlying need for medical or surgical care at the hospital **must be supported by complex medical factors such as history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event,** which review contractors will expect to be documented in the physician assessment and plan of care. CMS does not anticipate that physicians will include a separate attestation of the expected length of stay, but rather that this information may be inferred from

the physician's standard medical documentation, such as his or her plan of care, treatment orders, and physician's notes.

Q7: What factors should the physician take into consideration when making the admission decision and document in the medical record?

A7: For purposes of meeting the 2-midnight benchmark, in deciding whether an inpatient admission is warranted, the physician must assess whether the beneficiary requires hospital services and whether it is expected that such services will be required for 2 or more midnights. **The decision to admit the beneficiary as an inpatient is a complex medical decision made by the physician in consideration of various factors, including the beneficiary's age, disease processes, comorbidities, and the potential impact of sending the beneficiary home.** It is up to the physician to make the complex medical determination of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or whether the beneficiary may be discharged. If, based on the physician's evaluation of complex medical factors and applicable risk, the beneficiary may be safely and appropriately discharged, then the beneficiary should be discharged, and hospital payment is not appropriate on either an inpatient or outpatient basis. If the beneficiary is expected to require medically necessary hospital services for 2 or more midnights, then the physician should order inpatient admission and Part A payment is generally appropriate per the 2-midnight benchmark.

Federal Register /Vol. 79, No. 217 /Monday, November 10, 2014 /Rules and Regulations

XVI. Revision of the Requirements for Physician Certification of Hospital Inpatient Services Other Than Psychiatric Inpatient Services

The order must be supported by objective medical information for purposes of the Part A payment determinations. Thus, the physician order must be present in the medical record and be supported by the physician admission and progress notes in order for the hospital to be paid for hospital inpatient services.

The additional certification requirements now specified under § 424.13(a)(2), (a)(3), and (a)(4) *[sic]* (that is, the reason for hospitalization, the estimated time the patient will need to remain in the hospital, and the plan of posthospital care, if applicable) generally can be satisfied by elements routinely found in a patient's medical record, such as progress notes.

Acceptable Standards of Medical Care in the Community

Department of Health and Human Services, Health Care Financing Administration (1995, December). HCFA Ruling 95-1. Retrieved from http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/HCFAR951.pdf.

V. ACCEPTABLE STANDARDS OF PRACTICE—APPLICATION

"Medicare contractors, in determining what "acceptable standards of practice" exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts. "Published medical literature" refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the "New England Journal of Medicine" and the "Journal of the American Medical Association. " By way of example, consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine."

Justification of Treatment and Setting by Evidence Based Guidelines

Below are popular justifications related to standard of care and/ or risk for adverse events relevant to this DRG. Please note that all citations may not be relevant to your patient. Inapplicable material should be deleted.

<table>
<tr><td>Source/Reference</td><td>List of Medicare severity diagnosis-related groups (MS-DRGs) arithmetic mean length of stay – FY 2016 final rule. As found on: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html</td></tr>
<tr><td>Evidence Based Guideline/Practice Guideline Recommendation</td><td><table><tr><th>DRG</th><th>Arithmetic Mean LOS</th></tr><tr><td>204 RESPIRATORY SIGNS AND SYMPTOMS</td><td>2.8</td></tr></table></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Source/Reference</td><td>Peitz, G., Troyer, J., Jones, A., Shapiro, N., Nelson, R., Hernandez, J., Kline, K. (2014). Association of Body Mass Index With Increased Cost of Care and Length of Stay for Emergency Department Patients With Chest Pain and Dyspnea. Circulation: Cardiovascular Quality and Outcomes. As found on: http://circoutcomes.ahajournals.org/content/7/2/292.full.pdf</td></tr>
</table>

Evidence Based Guideline/Practice Guideline Recommendation	• "Obesity is highly relevant to the management of patients with chest complaints because it affects approximately one third of Americans and increases the risk of both cardiovascular and venous thromboembolic disease." [p. 292] • "High body mass index (BMI) increases the probability of indeterminate findings on diagnostic studies, length of stay, and cost of care for hospitalized patients." [p. 292]
Source/Reference	**Saguil, A., Fargo, M. (2012). Acute Respiratory Distress Syndrome: Diagnosis and Management. *American Family Physician*. As found on:** *http://www.aafp.org/afp/2012/0215/p352.html*
Evidence Based Guideline/Practice Guideline Recommendation	• "In-hospital mortality (in adults) related to (Acute Lung Injury [ALI] or Acute Respiratory Distress Syndrome [ARDS]) is between 34 and 55 percent." [p. 353] • "Risk factors include those causing direct lung injury (e.g., pneumonia, inhalation injury, pulmonary contusion) and indirect lung injury (e.g., nonpulmonary sepsis, burns, transfusion-related acute lung injury)." [p. 353] • "Risk factors for mortality include increasing age, worsening multiorgan dysfunction, presence of pulmonary and nonpulmonary comorbidities. higher Acute Physiology and Chronic Health Evaluation (APACHE) II score, and acidosis." [p. 353] • "Risk factors in children are similar to those in adults, with the addition of age-specific disorders, such as respiratory syncytial virus infection and near drowning aspiration injury." [p. 353] • Mortality rates for children between the ages of six months to 15 years of age, in a 2009 study, reported …a combined in-hospital mortality rate of 18 percent. [p. 353]
Source/Reference	**Daurat, A., Millet, I., Roustan, J-P., Maury, C., Taoirel, P., Jaber, S…Charbit, J. (2015). Thoracic Trauma Severity score on admission allows to determine the risk of delayed ARDS in trauma patients with pulmonary contusion. *Injury.* As found on:** *http://www.sciencedirect.com/science/article/pii/S0020138315005069*
Evidence Based Guideline/Practice Guideline Recommendation	• "The occurrence of pulmonary contusions was associated with higher mortality in several studies, especially because it frequently evolved to gas exchange impairment, delayed acute respiratory distress syndrome (ARDS) and/or multi-organ failure." [p. 147] • "These deleterious mechanisms may appear after a free interval of 24–48 h." [p. 147]

	• "Consequently, in trauma patients with pulmonary contusion, initial assessment may underestimate the gravity of the situation whereas respiratory status may worsen during the hours or days following admission." [p. 147] • 17% of patients with clinically relevant non-hypoxemia were at high risk to be misjudged or underestimated and almost one-fifth of this subgroup experienced delayed ARDS. [p. 151]
Source/Reference	**Earwood, J. S., Thompson, T. D. (2015). Hemoptysis: Evaluation and Management. *American Family Physician, Volume 91, Number 4, 243-249.* As found on:** *http://www.aafp.org/afp/2015/0215/p243.pdf*

Evidence Based Guideline/Practice Guideline Recommendation	• "Indications for Admission to the Intensive Care Unit or Referral to Specialty Center in Patients with Hemoptysis:
	  • Etiology with high risk of bleeding (e.g., aspergillosis, lesions with pulmonary artery involvement)
	  • Gas-exchange abnormalities (respiratory rate > 30 breaths per minute, oxygen saturation < 88% in room air, or need for high-flow oxygen [> 8 L per minute] or mechanical ventilation)
	  • Hemodynamic instability (hemoglobin < 8 g per dL [80 g per L] or a decrease of more than 2 g per dL [20 g per L] from baseline, consumptive coagulopathy, or hypotension requiring fluid bolus or vasopressors)
	  • Massive hemoptysis (> 200 mL per 48 hours or > 50 mL per episode in patients with chronic pulmonary disease)
	  • Respiratory comorbidities (e.g., previous pneumonectomy, chronic obstructive pulmonary disease, cystic fibrosis)
	  • Other comorbidities (e.g., ischemic heart disease, need for anticoagulation)" [p. 246]

Source/Reference	**Guilbert, T., Bacharier, L. (2011). Controversies in the Treatment of the Acutely Wheezing Infant. *American Journal of Respiratory and Critical Care Medicine,* 183(10), 1284–1285. As found on:** *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114055/*
Evidence Based Guideline/Practice Guideline Recommendation	• "Virus-induced wheezing in infants who have not experienced previous wheezing, termed bronchiolitis, leads to significant morbidity, and can be particularly difficult to treat." [p. 1284] • "Preschool children with wheezing experience disproportionately high morbidity and health care utilization, including a 50% greater rate of ambulatory visits, nearly double the rate of emergency

	department (ED) visits, and nearly triple the rate of hospitalization relative to school-age children." [p. 1284]
Source/Reference	**Cox, D., Bizzintino, J., Ferrari, G., Khoo, S., Zhang, G., Whelan, S., Lee, W…Souef, P. (2013). Human Rhinovirus Species C Infection in Young Children with Acute Wheeze is Associated with Increased Acute Respiratory Hospital Admissions.** ***American Journal of Respiratory and Critical Care Medicine, 188 (11), 1358-1364.*** **As found on:** *http://www.atsjournals.org/doi/full/10.1164/rccm.201303-0498OC#.Vr5GZulPrzU*
Evidence Based Guideline/Practice Guideline Recommendation	• "Human rhinovirus species C (HRV-C) is the most common cause of acute wheezing exacerbations in young children presenting to hospital." [1358] • "We found that, compared with other viruses, an HRV-C–related wheezing illness resulted in a twofold increase in the risk of subsequent respiratory admissions to a tertiary referral pediatric hospital, and the risk was further increased if the child was atopic [prone to developing allergic reactions]." [1361] • "The strong association of HRV-C infection with admissions to hospital with respiratory illnesses supports the likelihood that it is more pathogenic than other HRV species in children with more severe wheezing illnesses." [p. 1363]
Source/Reference	**Yehya, N., and Thomas, N.J. (2017). Disassociating Lung Mechanics And Oxygenation In Pediatric Acute Respiratory Distress Syndrome.** ***Crit Care Med., 45*****(7), 1232–1239. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474185/pdf/nihms853404.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Acute respiratory distress syndrome (ARDS) affects 45,000 children in the United States annually, with mortality approaching 30%. [p. 1233] • Absent targeted therapies, lung-protective ventilation remains the mainstay of treatment. [p. 1233] • Observational studies revealed no association between tidal volume (VT) and mortality in children. [p. 1233] • Peak inspiratory pressure (PIP) is consistently associated with mortality in pediatric ARDS. [p. 1233] • This is the first study to demonstrate that after adjusting for PaO2/FIO2, the pressure variables PIP, PEEP, ΔP, and Cdyn were not associated with mortality. [p. 1237] • Potentially, children with severe ARDS are more likely to die of organ failures unrelated to ARDS. [p. 1237]

	• Children more likely to survive demonstrate improved oxygenation, even if higher PaO2/FIO2 is not itself causal. [p. 1237] • The 2015 Pediatric Acute Lung Injury Consensus Conference recommendations for pediatric ARDS (22) suggest VT between 5 and 8 mL/kg, and lower (3 to 6 mL/kg) for severe disease, and to limit PIP, given prior associations with mortality. [p. 1237]
Source/Reference	**Spillane, N.T., Zamudio, S., Perez, J.A., Andrews, T., Nyirenda, T., Alvarez, M., and Al-Khan, A. (2018). Increased incidence of respiratory distress syndrome in neonates of mothers with abnormally invasive placentation. *PLoS ONE, 13*(7), 1-17. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6062082/pdf/pone.0201266.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Respiratory distress syndrome is predominantly a disease of the premature infant. [p. 2] • Respiratory distress syndrome is characterized by developmental insufficiency of surfactant production and function as well as pulmonary structural immaturity. [p. 2] • The incidence is inversely proportional to gestational age (GA), occurring in >90% in neonates less than 28 weeks. [p. 2] • A recent study has demonstrated the benefit of antenatal corticosteroid (ANC) administration in late preterm infants to prevent respiratory complications. [p. 2] • Several underappreciated risk factors for RDS are placenta previa [PP), a common cause of late preterm birth, and intrapartum bleeding. [p. 2] • The increased incidence of RDS has not been reported in the neonates of abnormally invasive placentation pregnancies, but it has been described in the infants of mothers with PP and vaginal bleeding due to other causes. [p. 13]
Source/Reference	**The Pediatric Acute Lung Injury Consensus Conference Group (2015). Pediatric Acute Respiratory Distress Syndrome: Consensus Recommendations From the Pediatric Acute Lung Injury Consensus Conference. *Pediatr Crit Care Med., 16*(5), 428–439. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5253180/pdf/nihms840146.pdf*
Evidence Based Guideline/Practice	• The new Berlin definitions (3) included several significant changes: 1) the ALI category was eliminated and replaced with a gradation of ARDS severity (mild, moderate, and severe) based on

Guideline Recommendation	the degree of oxygenation disturbance; 2) a minimum of 5 cm H2O of positive end-expiratory pressure (PEEP) was required; and 3) the determination of cardiac failure was rendered more subjective in view of the decreased utilization of pulmonary artery catheters. [p. 429] • Pulse oximetry is increasingly obviating the use of arterial blood gas measurement in pediatrics, and consequently, definitions requiring direct measurement of Pao2 may underestimate ARDS prevalence in children. [p. 429] • Pediatric Acute Lung Injury Consensus Conference recommends: a) Symptoms of hypoxemia and radiographic changes must occur within 7 days of a known clinical insult to qualify for PARDS. [p. 432] b) Chest imaging findings of new infiltrate(s) consistent with acute pulmonary parenchymal disease are necessary to diagnose PARDS. [p. 432] c) That OI, in preference to P/F ratio, should be the primary metric of lung disease severity to define PARDS for all patients treated with invasive mechanical ventilation. [p. 432] d) OSI should be used when an OI is not available for stratification of risk for patients receiving invasive mechanical ventilation. [p. 432] e) That to apply Spo2 criteria to diagnose PARDS, oxygen therapy should be titrated to achieve the Spo2 between 88% and 97%. [p. 433] f) Patients with cyanotic congenital heart disease are considered to have PARDS if they fulfill standard criteria (acute onset, a known clinical insult, and chest imaging supporting new onset pulmonary parenchymal disease) and have an acute deterioration in oxygenation not explained by the underlying cardiac disease. [p. 433] g) Predicted body weight for patients with poor respiratory system compliance and closer to the physiologic range (5–8 mL/kg ideal body weight) for patients with better preserved respiratory system compliance. [p. 435] h) High-frequency oscillatory ventilation (HFOV) should be considered as an alternative ventilatory mode in hypoxic respiratory failure in patients in whom plateau airway pressures exceed 28 cm H2O in the absence of clinical evidence of reduced chest wall compliance. [p. 436]

	i) Cuffed endotracheal tubes (ETTs) are recommended when conventionally ventilating a patient with PARDS. [p. 437] j) Permissive hypercapnia should be considered for moderate-to-severe PARDS to minimize ventilator-induced lung injury. [p. 437] k) Intubation should be considered in patients receiving NPPV who do not show clinical improvement or have signs and symptoms of worsening disease, including increased respiratory rate, increased work of breathing, worsening gas exchange, or an altered level of consciousness. [p. 444] l) Extracorporeal membrane oxygenation (ECMO) should be considered to support children with severe PARDS where the cause of the respiratory failure is believed to be reversible or the child is likely to be suitable for consideration for lung transplantation. [p. 445] m) Non-intubated children within the definition of PARDS (or at risk) acknowledges the increasing use of noninvasive positive pressure support and focuses appropriate attention on possible early intervention in PARDS. [p. 447]
Source/Reference	**Lee, K.Y. (2017). Pneumonia, Acute Respiratory Distress Syndrome, and Early Immune-Modulator Therapy. *Int. J. Mol. Sci.*, 18(388), 1-15. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5343923/pdf/ijms-18-00388.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Acute respiratory distress syndrome (ARDS) is caused by infectious insults, such as pneumonia from various pathogens or related to other noninfectious events. [p. 1] • Treatment with early systemic immune modulators (corticosteroids and/or intravenous immunoglobulin) as soon as possible may reduce aberrant immune responses in the potential stage of ARDS. [p. 1] • By the Berlin definition, diagnostic hypoxemia is defined as decreased arterial PaO2/FiO2 ratio with parameters of 201–300 mmHg for mild ARDS, 101–200 mmHg for moderate ARDS, and ≤100 mmHg for severe ARDS. [p. 1] • Infectious factors such as pneumonia with/without sepsis caused by a variety of pathogens, including pneumococci, influenza viruses, coronaviruses, and malaria can be the cause of ARDS. [p. 1]

	• Various non-infectious factors, such as aspiration of gastric contents, near drowning, blunt chest contusion, multiple injuries, inhalation burns, pancreatitis, and multiple blood transfusions are associated with ARDS. [p. 2] • Early antimicrobial therapy, such as the provision of antibiotics and antivirals, for pathogen-induced pneumonia is critical to reduce the number of pathogens and pathogen-originated substances, thereby inducing early recovery from the disease. [p. 7]
Source/Reference	**Zubrow, M.E., Thomas, N.J., Friedman, D.F., and Yehya, N. (2018). Red blood cell transfusions are associated with prolonged mechanical ventilation in pediatric acute respiratory distress syndrome. *Pediatr Crit Care Med, 19*(2), 88–96. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5796837/pdf/nihms912479.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Acute respiratory distress syndrome (ARDS) is a heterogeneous syndrome of diverse etiologies of hypoxemic respiratory failure. [p. 89] • Transfusion of red blood cells (RBC) is frequently prescribed in order to maximize oxygen delivery during hypoxemia. [p. 89] • Previous literature has revealed conflicting results with regards to outcomes associated with transfusions of blood products in PARDS. [p. 94] • Previous studies in PARDS have shown that increasing fluid positivity early in PARDS patients is associated with increased mortality and fewer ventilator free days. [p. 94] • Transfusion related acute lung injury (TRALI) is a well described phenomenon in which respiratory distress develops within 6 hours post transfusion of blood products. [p. 94] • FFP has a higher incidence of transfusion related acute lung injury than RBC in prior studies. [p. 94] • There is accumulating evidence in critically ill pediatric patients that transfusion may negatively impact respiratory function. [p. 95] • RBC transfusion is associated with prolonged duration of mechanical ventilation. [p. 96]
Source/Reference	**Sweet, L.R. et al. (2017). Respiratory distress in the neonate: Case definition & guidelines for data collection, analysis, and presentation of maternal immunization safety data. *Vaccine, 35*(2017), 6506–6517.**

	Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5710987/pdf/main.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Respiratory distress is one of the most common problems neonates encounter within the first few days of life. [p. 6506] • According to the American Academy of Pediatrics, approximately 10% of neonates need some assistance to begin breathing at birth, with up to 1% requiring extensive resuscitation. [p. 6506] • Neonates with respiratory distress are 2–4 times more likely to die than neonates without respiratory distress. [p. 6506] • Clinical symptoms most commonly cited as indicators of respiratory distress include tachypnea, nasal flaring, grunting, retractions, (subcostal, intercostal, supracostal, jugular), and cyanosis. [p. 6507] • The most common causes of respiratory distress in the newborn are pulmonary in origin and include transient tachypnea of the newborn, respiratory distress syndrome, meconium aspiration syndrome, pneumonia, sepsis, pneumothorax, persistent pulmonary hypertension of the newborn, and delayed transition. [p. 6507] • Transient Tachypnea of the Neonate (TTN) is the most common etiology of respiratory distress in the neonatal period. [p. 6507] • Transient Tachypnea of the Neonate presents within the first two hours after birth and can persist for up to 72 h. [p. 6507] • The disease progresses rapidly, with increased work of breathing, intrapulmonary shunting, ventilation perfusion mismatch, and hypoxia with eventual respiratory failure. [p. 6507] • Assessment for respiratory distress should include at least some of the following parameters: (1) measurement of respiratory rate (normal 40–60); (2) observation for increased work of breathing: inspiratory sternal, intercostal and subcostal recession/indrawing, tracheal tug; (3) assessment for airway noises such as expiratory grunting or inspiratory stridor; (4) assessment for nasal flaring or head bobbing; (5) assessment of color for cyanosis, ideally pulse oximetry measurement should be obtained if any concern about color/cyanosis. [p. 6508] • Radiology findings are helpful for the identification of etiologic causes of respiratory distress in the newborn, specifically for the identification of pulmonary vs. extrapulmonary causes of respiratory distress. [p. 6511] • Laboratory findings are helpful for the identification of etiologic causes of respiratory distress in the newborn. [p. 6511]

Source/Reference	**Amigoni, A., Pettenazzo, A., Stritoni, V., and Circelli, M. (2017). Surfactants in Acute Respiratory Distress Syndrome in Infants and Children: Past, Present and Future. *Clin Drug Investig, 37*(2017), 729–736. Retrieved from:** *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5509808/pdf/40261_2017_Article_532.pdf*
Evidence Based Guideline/Practice Guideline Recommendation	• Lack of surfactant results in respiratory failure, secondary to atelectasis, alveolar flooding and severe hypoxemia. [p. 731] • Since the advent of exogenous surfactant replacement therapy, mortality from respiratory distress syndrome in neonates has been reduced by >50%. [p. 731] • Exogenous surfactant may improve outcomes in infants and children. [p. 732] • One of the early studies by Auten et al., in full-term neonates with respiratory failure associated with pneumonia and meconium aspiration syndrome, showed that intratracheal calf lung surfactant significantly improved oxygenation. [p. 732] • Intratracheal surfactant moderately improved oxygenation in children with secondary pulmonary pathology or systemic disease. [p. 733] • Willson et al. study showed intratracheal administration of calfactant was well tolerated and associated with a rapid improvement in oxygenation, earlier extubation and decreased requirement for intensive care. [p. 733] • Bronchoalveolar lavage (BAL) with normal saline and surfactant has the advantage of facilitating a synergistic effect that allows removal of inhaled material, the recruitment of non-ventilating areas and the maintenance of surfactant pool size. [p. 733]
Source/Reference	**Jyrkka J, et al. (2009). Polypharmacy status as an indicator of mortality in an elderly population [Abstract]. Drugs Aging. 26(12):1039-48. As found on p. 1039:** *http://www.ncbi.nlm.nih.gov/pubmed/19929031*
Evidence Based Guideline/Practice Guideline Recommendation	• Polypharmacy is six to nine drugs • Excessive polypharmacy is ten or more drugs • The mortality rate was 37% in the first phase [elderly persons aged>or=75 years] and 40% in the second phase [second phase aged>or=80 years]. • Excessive polypharmacy is an indicator for mortality in the elderly • Age, male sex and Activities of Daily Living dependency were associated with mortality in both phases

Source/Reference	**Falciglia M, Freyberg RW, Almenoff PL, D'Alessio DA, et al. (2009). Hyperglycemia-Related Mortality in Critically Ill Patients Varies with Admission Diagnosis. Crit Care Med. 37(12): 3001–3009. As found on:** *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2905804/*
Evidence Based Guideline/Practice Guideline Recommendation	• "Hyperglycemia was associated with increased mortality independent of illness severity." [p. 3001] • Mortality related to hyperglycemia had a clear association with acute myocardial infarction, arrhythmia, unstable angina, and pulmonary embolism. [pp. 3001-3002] • "Hyperglycemia was associated with increased mortality independent of ICU type, length of stay and diabetes." [p. 3002]
Source/Reference	**Umpierrez GE, Isaacs SD, Bazargan N, You X, et al. (2002). Hyperglycemia: An Independent Marker of In-Hospital Mortality in Patients with Undiagnosed Diabetes. The Journal of Clinical Endocrinology & Metabolism 87(3):978–982. As found on:** *http://jcem.endojournals.org/content/87/3/978.full.pdf+html*
Evidence Based Guideline/Practice Guideline Recommendation	• New hyperglycemia was considered a fasting glucose of $\geq$ 126, or a random blood glucose $\geq$ 200 on 2 or more determinations [p. 978] • "Newly discovered hyperglycemia was associated with higher in-hospital mortality rate (16%) …" [p. 978] • "New hyperglycemic patients had a longer length of hospital stay …" [p. 978] • In-hospital hyperglycemia is an important marker of poor clinical outcome and mortality with and without diabetes [p. 978] • Patients with newly diagnosed hyperglycemia had a higher mortality rate than patients with diabetes or normoglycemia [p. 978]

Regulatory Arguments

1) Limitation on Liability

«Facility» did not know, and could not reasonably have been expected to know, that payment would not be made for the services provided and therefore this claim meets the statutory criteria of the Social Security Act § SEC. 1879. [42 U.S.C. δ 1395pp] to allow payment for such claims.

Additionally, reimbursement to «Facility» for the same services on other claims prior to the instant case and subsequent to the case would not be considered notice of non-payment for such services.

Section 1879. [42 U.S.C. δ 1395pp] of the Social Security Act provides that payment can be made for certain denied claims if two (2) criteria are met under a "limitation on liability" provision. These criteria are: (1) a determination is made that, by reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii), and (2) the provider or beneficiary of services "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B."

«Facility» did not have actual or constructive knowledge that this claim would be denied. A provider is considered to have known that the services were not covered if the provider had notice. The Code of Federal Regulations 42 C.F.R. δ 411.406 state that the "criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary are as follows:

(a) Basic rule. A provider, practitioner, or supplier that furnished services which constitute custodial care under Sec. 411.15(g) or that are not reasonable and necessary under Sec. 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) Notice from the PRO, intermediary or carrier. The PRO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) Notice from the utilization review committee or the beneficiary's attending physician. The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) Notice from the provider, practitioner, or supplier to the beneficiary. Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that--

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) Knowledge based on experience, actual notice, or constructive notice."

Knowledge may be imparted to a provider in several ways. However, the evidence must be clear and convincing that the provider could have been expected to know. This section further provides that "It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a PRO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community."

2) Treating or Attending Physician Rule

«Patient_First» «Patient_Last» was certified for admission at «Facility» by a physician who determined that such services were medically necessary and reasonable; there is no evidence to the contrary supporting the payer's denial that such services were not medically necessary and reasonable.

The treating or attending physician rule as applied in the Fourth Circuit requires that the treating physician's opinion "be given great weight and may only be disregarded if there is persuasive contradictory evidence" in the record. Coffman v. Bowen, 829 F.2d 514, 517 (4th Cir. 1987), superseded by Statute for the purpose of Social Security Disability claims, 20 C.F.R. § 404.1527(d) (2) (1991); superseded by Regulation, see Winford v. Charter, 917 F. Supp. 398, 400 (E.D. Va. 1996).

The rationale for this rule is that the treating physician's opinion "reflects an expert judgment based on a continuing observation of the patient's condition over a prolonged period of time." Mitchell v. Schweiker, 699 F.2d 185, 187 (4th Cir. 1983), superseded by Regulation for the purpose of Social Security Disability claims, 20 C.F.R. § 404.1527(d) (2) (1991). See Ward v. Charter, 924 F.Supp. 53, 55 (W.D. Va. 1996).

Although the "treating or attending physician rule" is typically applied in Social Security disability cases, see id, the rule has been held to be of even greater force in the context of Medicare reimbursement. Hill v. Sullivan, 1991 W.L. 417526 (W.D.N.Y. 1991); Gartmann v. Secretary, 633 F. Supp. 671, 680 (E.D. N.Y. 1986).

Indeed, the legislative history of the Medicare statute clearly states, "the physician is to be the key figure in determining utilization of health services." 1965 U.S. Code Cong. & Ad. News, 1943, 1986; Gartmann, 633 F. Supp. At 681; Hultzman v. Weinberger, 495 F.2d 1276, 1279 (3d Cir. 1974); Reading v. Richardson, 339 F. Supp. 295, 300-01 (E.D. Mo. 1972); see also Kuebler v. Secretary, 579 F. Supp. 1436, 1440 (E.D. N.Y. 1984); Breeden v. Weinberger, 377 F. Supp. 734, 737 (M.D. La. 1974).

Recent regulations from the Social Security Administration provide that when evaluating disability claims the administration will "give more weight to opinions from treating sources" and if a treating source's opinion is "well-supported by medically acceptable clinical and laboratory diagnostic techniques and is not inconsistent with the other substantial evidence in the case record, it will be given controlling weight." 20 C.F.R. § 404.1527(d) (2) (1991). See Ward v. Charter, 924 F. Supp. 53 (W.D. Va. 1996).

The physician certified that «Patient_First» «Patient_Last» met all admission and continuing treatment criteria under the Medicare guidelines. The only medical opinion in the record determines that treatment rendered «Patient_First» «Patient_Last» was medically necessary and reasonable. This medical opinion should be given controlling weight. There is no evidence that «Patient_First» «Patient_Last» did not require the intensity of services ordered and provided.

«Patient_First» «Patient_Last»'s treatment was clearly ordered by the treating physician as being required medical treatment. In the case now under appeal, a qualified physician clearly certified that «Patient_First» «Patient_Last» required the medical treatment delivered by «Facility». The services rendered were deemed by the physician to be reasonable and necessary for the active treatment of the patient's condition. «Facility» relied on this opinion in treating «Patient_First» «Patient_Last» during the denied period.

Conclusion

«Facility» provided medically necessary services to «Patient_First» «Patient_Last» with the expectation that those services would be reimbursed according to the documentation in all payer communications. «Facility» respectfully requests that you reconsider this claim and require payment to be made to «Facility» for the services provided to «Patient_First» «Patient_Last» in this case.

I appreciate your attention to this matter and invite you to contact me should you have any questions.

Respectfully,

Image_Signature

«Facility_Signature»

Submitted with the authority of the Provider,

Please return all correspondence to:

«Facility_Description»

NPI: «Facility_NPI»
Tax ID: «Facility_Tax_ID»
PTAN: «PTAN»
«TableEnd:PATIENTINFO»