

Clinical Policy Title: Room humidifiers

Clinical Policy Number: CCP.1281

Effective Date: February 1, 2017
Initial Review Date: November 16, 2016
Most Recent Review Date: January 8, 2019

Next Review Date: January 2020

Policy contains:

- Indoor air humidification.
- Room/home humidifier.

Related policies:

CCP.1126 Noninvasive positive pressure ventilation in adults

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state-or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of room humidifiers (i.e. cool mist humidifiers) to be investigational and, therefore, not medically necessary. Consequently, room humidifiers do not qualify as durable medical equipment (Bott, 2009; Donnelly, 2006; Fisk, 2012; Gao, 2014; Moore, 2007; Peters, 2014; Restrepo, 2012; Singh, 2013; Wallace, 2008).

This policy does not address devices that provide warm mist humidification (i.e. vaporizers) of inspired gases for persons with artificial airways, receiving invasive or noninvasive ventilation, or on supplemental oxygen.

Limitations:

All other uses of room humidifiers are not medically necessary.

Alternative covered services:

None.

Background

Relative humidity affects air quality and the perception of comfort indoors. High humidity can create condensation on walls and trigger the growth of harmful bacteria, dust mites and molds. The U.S. Environmental Protection Agency recommends maintaining indoor relative humidity below 60 percent (ideally between 30 and 50 percent) to reduce mold growth (Environmental Protection Agency, 2012). Conversely, humidity below this range can cause complaints related to dryness in many parts of the body (e.g., dry skin, nose, throat, and lips).

In the home, room humidifiers are used to increase the relative humidity of ambient air. Two general types are warm mist and cool mist (Consumer Reports, 2016). Warm mist humidifiers (also called vaporizers) heat water to a boil and release the resulting steam. To produce cool mist, evaporative, ultrasonic, and impeller types use either a fan to blow air over a wet wick, a vibrating nebulizer, or a rotating disk, respectively.

The U.S. Food and Drug Administration regulates humidifiers when the device adds water vapor to breathing gases and is intended for respiratory therapy or other medical purposes. The vapor must pervade the area surrounding the patient, who breathes the vapor during normal respiration (21CFR868.5460). The Food and Drug Administration does not regulate most room humidifiers, since they claim only to improve room comfort.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on October 23, 2018. Search terms were: "Durable Medical Equipment" (MeSH), "Humidifiers" (MeSH), "Humidity/therapeutic use" (MeSH), "Humidity/therapy" (MeSH), "Respiratory Therapy" (MeSH), and free text terms "room humidifier," "home humidifier," and "humidity."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes sometimes referred to as efficiency studies which also rank near the top of evidence hierarchies.

Findings

We identified five systematic reviews/meta-analyses and four clinical practice guidelines for this policy. There is a lack of high quality evidence from randomized controlled trials demonstrating improvement in health outcomes associated with using room humidifiers with or without heat for treatment of the common cold, croup (Moore, 2007), or in children with prolonged non-specific cough (Donnelly, 2006).

Two practice parameters developed jointly by the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology did not recommend room humidifiers as an environmental control intervention in the management of either rhinitis or rhinosinusitis (Wallace, 2008; Peters, 2014). While there is stronger evidence for recommending humidification of inspired gases in persons with artificial airways, on invasive ventilation, or receiving supplemental oxygen, neither the American Association for Respiratory Care, the British Thoracic Society, nor the Association of Chartered Physiotherapists in Respiratory Care guidelines found sufficient evidence to recommend humidification in non-intubated patients (Bott, 2009; Restrepo, 2012). The Healthy Children website of the American Academy of Pediatrics (2015; 2017) recommends using a cool-mist vaporizer, but not hot-water vaporizers, in a child's room to treat a stuffy nose, keep nasal passages moist, and improve comfort.

One systematic review and one meta-analysis demonstrated an association between increased ambient humidity and dampness and mold, which, in turn, are associated with the rate of certain climate-sensitive health conditions, particularly respiratory illnesses among children (Fisk, 2010; Gao, 2014). However, there is less certainty as to the direction and magnitude of these effects, likely due to heterogeneity in study designs and environmental differences across studies.

In summary, humidification of indoor air may improve comfort, but the evidence supporting improvement in physiologic measures is inconclusive. From a respiratory therapy perspective, adequate humidification is important for preventing retained secretions in persons with certain chronic respiratory conditions, but the evidence of effectiveness of room humidifiers in a community or home setting needs further exploration. At present, the evidence for their benefit does not exceed the potential health risks associated with excessive humidification and poor infection control practices related to the equipment.

Policy updates:

Two resources were added to the Professional Society Guideline section in the January, 2018 update. No new literature was identified in October, 2018. Policy ID changed from 17.02.05 to CCP. 1281

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Gao (2014)	Key points:

Citation	Content, Methods, Recommendations
Effects of ambient humidity on child health	 Systematic review of 37 observational studies in which humidity was one of the exposure indicators of interest. Overall quality: moderate to high. Ambient humidity generally plays a significant role in the incidence and prevalence of childhood climate-sensitive diseases, especially for gastrointestinal, respiratory system, and allergic diseases. The direction and magnitude of these effects are inconsistent, possibly due to study designs, regional and local characteristics (e.g., geographical environment, type of climate, vegetation condition, air quality, and socio-economic status), and the acclimatization and adaptation of the local populations.
Peters (2014) for the	Key points:
American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology	No mention of room humidifiers for environmental control.
Practice parameter: Diagnosis and management of rhinosinusitis:	
Singh (2013)	Key points:
Cochrane review Heated, humidified air for the common cold	 Systematic review of heated, humidified air delivered from a handheld device as studied in six randomized clinical trials (394 total participants). Overall quality: Moderate-to-high with low risk of bias but small sample sizes. Three randomized clinical trials in which patient data could be pooled found benefits of steam for symptom relief for the common cold (odds ratio [OR] 0.31, 95% confidence interval [CI] 0.16 to 0.60). Other three randomized clinical trials found no effects. Equivocal results on symptom indices. Minor side effects (including discomfort or irritation of the nose) were reported in some studies. No decrease in viral culture titers in the nasal secretions of the participants. Steam inhalation is not recommended in the routine treatment of common cold symptoms until more double-blind, randomized clinical trials with a standardized treatment modality are conducted.
Restrepo (2012) for the	Key points:
American Association for Respiratory Care Humidification during invasive and noninvasive mechanical ventilation (NIV)	 Practice guideline based on 184 clinical trials and systematic reviews, and 10 articles. No clear consensus on whether additional heat and humidity are always necessary when the upper airway is not bypassed (e.g., in noninvasive mechanical ventilation). Experts suggest active humidification to improve comfort.
Fisk (2010)	Key points:

Citation	Content, Methods, Recommendations
Association of residential dampness and mold with respiratory tract infections and bronchitis	 Meta-analysis of 23 observational studies (> 50,000 total subjects). Quality assessment: Not reported. Little effect of publication bias. Results (OR, 95% CI): Bronchitis (1.45, 1.32 to 1.59). Respiratory infections (1.44, 1.31 to 1.59); respiratory infections excluding nonspecific upper respiratory infections (1.50, 1.32 to 1.70). Respiratory infections in children or infants (1.48, 1.33 to 1.65). Estimated attributable risk proportions ranged from 8% to 20%. Building dampness and mold are associated with moderate but statistically significant increases in respiratory infections and bronchitis.
Bott (2009) for the British Thoracic Society and tthe Association of Chartered Physiotherapists in Respiratory Care (UK) Guidelines for the physiotherapy management of the adult, medical, spontaneously	Key points: There is little evidence for the use of humidification in non-intubated patients. Research into the short- and longer term effects of humidification, particularly with supplemental oxygen, is required. Large-volume nebulization-based humidifiers (cold and warm systems) are a potential infection risk, but may be useful for patients with sputum retention.
breathing patient Wallace (2008) for the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology Practice parameter: Diagnosis and	Because cool mist humidifiers may be reservoirs for bacteria and fungi, they are best avoided.
management of rhinitis Moore (2007) Humidified air inhalation	Key points:
for treating croup	 Systematic review and meta-analysis of three studies comprising 135 total patients with moderate croup treated with warm or cool humidified air delivered by steam or humidified tent in the inpatient, emergency department or community setting. Results marginally favored the treatment group (treatment duration of 20 to 60 minutes) with a weighted standardized mean difference of -0.14 (95% CI -0.75 to 0.47). No significantly different outcomes between the groups. Insufficient evidence to exclude either a small beneficial or a harmful effect.
Donnelly (2006) Cochrane review	 No randomized clinical trials of the efficacy of air-modification modalities, (ionizers, vaporizers, humidifiers, air filters, regular vacuuming) found.

Citation	Content, Methods, Recommendations
Indoor air modification	Insufficient evidence to make recommendations.
interventions for	
prolonged non-specific	
cough in children	

References

Professional society guidelines/other:

American Academy of Pediatrics. Safety and Prevention. Caring for Your Child's Cold or Flu. June 26, 2018. https://www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/How-to-Manage-Colds-and-Flu.aspx. Accessed October 23, 2018.

American Academy of Pediatrics. Safety and Prevention. Coughs and colds: Medicines or home remedies? June 26, 2018. https://www.healthychildren.org/English/health-issues/conditions/chest-lungs/Pages/Coughs-and-Colds-Medicines-or-Home-Remedies.aspx. Accessed October 23, 2018.

Bott J, Blumenthal S, Buxton M, et al. Guidelines for the physiotherapy management of the adult, medical, spontaneously breathing patient. *Thorax*. 2009; 64 Suppl 1: i1-51. doi: 10.1136/thx.2008.110726.

Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol.* 2014; 113(4): 347-385. doi: 10.1016/j.anai.2014.07.025.

Restrepo RD, Walsh BK. Humidification during invasive and noninvasive mechanical ventilation: 2012. *Respir Care.* 2012; 57(5): 782-788. doi: 10.4187/respcare.01766.

Snellman L, Adams W, Anderson G, Godfrey A, Gravley A, Johnson K, Marshall P, Myers C, Nesse R, Short S. Institute for Clinical Systems Improvement. Diagnosis and treatment of respiratory illness in children and adults. http://bit.ly/RespIII. Updated January 2013.

Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol.* 2008; 122(2 Suppl): S1-84. doi: 10.1016/j.jaci.2008.06.003.

Peer-reviewed references:

Donnelly D, Everard MM, Chang AB. Indoor air modification interventions for prolonged non-specific cough in children. *Cochrane Database Syst Rev.* 2006; (3): CD005075. doi: 10.1002/14651858.CD005075.pub2.

Fisk WJ, Eliseeva EA, Mendell MJ. Association of residential dampness and mold with respiratory tract infections and bronchitis: a meta-analysis. *Environ Health*. 2010; 9: 72. doi: 10.1186/1476-069X-9-72.

Gao J, Sun Y, Lu Y, Li L. Impact of ambient humidity on child health: a systematic review. *PLoS One.* 2014; 9(12): e112508. doi: 10.1371/journal.pone.0112508.

Humidifier Buying Guide. Consumer Reports website. August, 2016. http://www.consumerreports.org/cro/humidifiers/buying-guide.htm. Accessed October 23, 2018.

Moore M, Little P. Humidified air inhalation for treating croup: a systematic review and meta-analysis. *Fam Pract.* 2007; 24(4): 295 – 301. doi: <u>10.1093/fampra/cmm022</u>.

Singh M, Singh M. Heated, humidified air for the common cold. *Cochrane Database Syst Rev.* 2013; (6): Cd001728. doi: 10.1002/14651858.CD001728.pub5.

U.S. Environmental Protection Agency. A brief guide to mold, moisture, and your home. EPA 402-K-02-003. Environmental Protection Agency website. Reprinted September, 2012. https://www.epa.gov/sites/production/files/2016-10/documents/moldguide12.pdf. Accessed October 23, 2018.

Centers for Medicare & Medicaid Services National Coverage Determinations:

Pub 100-2. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. (Rev. 241, 02-01-18). https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed October 23, 2018.

Local Coverage Determinations:

No Local Coverage Determinations identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

ICD-10 Code	Description	Comments
Non-specific	Not Applicable	

CPT Code	Description	Comments
N/A	Not Applicable	

HCPCS Level II Code	Description	Comments
E0605	Vaporizer, home type	Not covered for cool mist humidification. Covered only for warm mist humidification of inspired gases for persons with artificial airways,
		receiving invasive or non-invasive ventilation, or

HCPCS Level II Code	Description	Comments
		on supplemental oxygen.