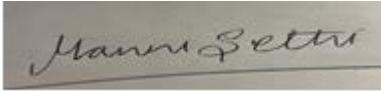


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community Health Choices	Submission Date: 2/1/2024
Policy Number: ccp.1281	Effective Date: 2/2017 Revision Date: January 1, 2024
Policy Name: Room humidifiers	
Type of Submission – Check all that apply: <div style="margin-left: 20px;"><input checked="" type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL</div>	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: <div style="color: red; margin-top: 10px;">Previously retired. Reactivated policy. Now requires Prior authorization.</div>	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 



Room humidifiers

Clinical Policy ID: CCP.1281

Recent review date: 1/2024

Next review date: 5/2025

Policy contains: Indoor air humidification; room/home humidifier.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Keystone First Community HealthChoices 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. Keystone First Community HealthChoices' 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. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The use of room humidifiers (i.e. cool mist humidifiers) is investigational/not clinically proven and, therefore, not medically necessary. Consequently, room humidifiers do not qualify as durable medical equipment.

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

No alternative covered services were identified during the writing of this policy.

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 (2012) recommends maintaining indoor relative humidity below 60% (ideally between 30 and 50%) to reduce mold growth. 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, 2023).

Warm mist humidifiers (also called vaporizers) heat water to a boil and release the resulting steam. Evaporative, ultrasonic, and impeller types use either a fan to blow air over a wet wick, a vibrating nebulizer, or a rotating disk,

respectively, to produce cool mist. Humidifiers (hygrometers) increased humidity within a room, versus an external environment, by 7.50%, when placed 1-2 meters from the room occupant (Guerra, 2021).

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 U.S. Food and Drug Administration does not regulate most room humidifiers, since they claim only to improve room comfort.

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).

There is stronger evidence for recommending humidification of inspired gases in persons with artificial airways, on invasive ventilation, or receiving supplemental oxygen. However, neither the guidelines published by the American Association for Respiratory Care (Restrepo, 2012), nor joint guidelines published by the British Thoracic Society and the Association of Chartered Physiotherapists in Respiratory Care (Bott, 2009) found sufficient evidence to recommend humidification in non-intubated patients. The Healthy Children website of the American Academy of Pediatrics (2022; 2023) 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.

The Institute of Clinical Systems Improvement guideline cautions against risks posed by humidifiers. These risks include the ability of micro-organisms to grow easily unless properly cleaned; the risk of children being burned by hot water in the humidifier; and the ability of humidifiers to cause mildew growth (Snellman, 2013).

One systematic review (Gao, 2014) and one meta-analysis (Fisk, 2010) demonstrated an association between increased ambient humidity and dampness and mold, which, in turn, is associated with the rate of certain climate-sensitive health conditions, particularly respiratory illnesses among children. 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.

A systematic review of 12 articles documented microbial contamination in reusable hospital humidifiers, and a low risk of contamination during the first weeks of use of prefilled humidifiers, which allows multiple use in different patients, with no risk of cross-contamination. Authors suggest replacing reusable humidifiers with prefilled models to decrease contamination to patients (Fuente-Sancho, 2019).

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.

In 2018, we identified no newly published, relevant literature to add to the policy.

In 2019, we identified no newly published, relevant literature to add to the policy. The policy ID was changed from CP# 17.02.05 to CCP. 1281.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we replaced Singh (2013) with an update of the review (Singh, 2017) with no changes to the policy.

In 2022, we added one systematic review and one Medicare coverage reference, with no changes to the policy.

In 2023, we added a systematic review included nine studies (n = 574) that showed adding humidification devices used by patients with obstructive sleep apnea reduced throat dryness and improved outcomes from continuous positive airway pressure machines (Kennedy, 2019).

In 2024, we added a Cochrane review of 12 studies (n = 4,447) that concluded humidification of indoor air in schools and the work place did not reduce dryness symptoms; data on improvements in absenteeism after humidification is limited (Byber, 2021).

We also added a systematic review that found fill water quality used in rooms in portable ultrasonic air humidifiers resulted in emission of particles that are inhaled, which can cause adverse respiratory health outcomes in adults and children (Dietrich, 2022).

References

On October 24, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Durable Medical Equipment” (MeSH), “Humidifiers” (MeSH), “Humidity/therapeutic use” (MeSH), “Humidity/therapy” (MeSH), “Respiratory Therapy” (MeSH), “room humidifier,” “home humidifier,” and “humidity.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/2016: initial review date and clinical policy effective date: 2/2017

1/2018: Policy references updated.

1/2019: Policy references updated. Policy ID changed.

1/2020: Policy references updated.

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.