Pulse oximetry is a telemetric adjunct to direct arterial oxygen pressure measurement useful to monitor systemic oxygenation (SpO2) on both an intermittent and a continuous basis. With advancing miniaturization of medical electronics and improved sensing nodes, pulse oximetry has won a place as the default non-invasive and portable means of following patients at risk of hypoxemia of both acute and chronic character.\(^1,2,3,4\)

The emerging interest in electronic at-home measurement of body function has fostered a wave of development for these devices intended to put the technology into the hands of more constituents. Patients with pulmonary disease (e.g., chronic obstructive pulmonary disease [COPD]), circulatory disease including congenital defects of the heart and lungs (e.g., pulmonary dysplasia), and disturbances in oxygen delivery at the tissue level (e.g., peripheral vascular disease [PVD] in patients with diabetes mellitus) may theoretically benefit from such close monitoring.\(^5,6\)

The pitfalls of pulse oximetry are several: there is conjecture that ambient light may at times interfere with the measure of SpO2 and give a misleading assessment of actual arterial oxygen pressure (PaO2). Physically active patients, pediatric patients and patients at sleep may inadvertently displace or remove the monitor. Furthermore, device-device electrical and wireless interference may cause inconsistencies or errors in measurement. To this end, some authorities emphasize that periodic formal arterial blood gas (ABG) measurement is mandatory to double-check the readings from the pulse oximeter.

Baptist Health Plan considers the use of devices for continuous or intermittent measurement of systemic oxygenation by at-home pulse oximetry to be to be clinically proven and, therefore,
medically necessary when any one of the following criteria is met:

- Members on home mechanical ventilation
- Members receiving home oxygen therapy
- Members being weaned from home oxygen therapy
- Infants and children with a diagnosis of bronchopulmonary dysplasia
- Members who are being monitored for the need for home oxygen therapy with a diagnosis of any one of the following:
  - Chronic obstructive pulmonary disease (COPD), or
  - Severe cardiopulmonary disease, or
  - Neuromuscular disease affecting the lungs.

Baptist Health Plan considers the use of devices for continuous or intermittent measurement of systemic oxygenation by at-home pulse oximetry to be investigational, and therefore **not medically necessary for the following indications:**

- Asthma management
- Stable respiratory conditions
- Members using continuous positive airway pressure (CPAP) devices
- Diagnosis of obstructive sleep apnea

**MEDICAL BACKGROUND**

A systematic review inclusive of 6629 subjects (median age of 60-74 years and a median duration of diabetes of 9-24 years) noted that ankle brachial index (ABI) was the most widely assessed index test for PVD. Overall, the positive likelihood ratio and negative likelihood ratio (NLR) of an ABI threshold <0.9 ranged from 2 to 25 (median 8) and <0.1 to 0.7 (median 0.3), respectively. In patients with neuropathy, the NLR of the ABI was generally higher (two out of three studies), indicating poorer performance, and ranged between 0.3 and 0.5. A toe brachial index <0.75 was associated with a median positive likelihood ratio and NLRs of 3 and ≤0.1, respectively, and was less affected by neuropathy. Pulse oximetry used to measure the oxygen saturation of peripheral blood and Doppler waveform analyses had NLRs of 0.2 and <0.1. The authors concluded that the performance of ABI for the diagnosis of PAD in patients with diabetes mellitus is variable and is adversely affected by the presence of neuropathy; and that limited evidence suggests that toe brachial index, pulse oximetry and waveform analysis may be superior to ABI for diagnosing PVD in patients with neuropathy with and without foot ulcers.

Hayes (2016) reported that there is no significant impact of ambient light on pulse oximetry, though the literature continues to allude to the potential artefactual effect of ambient light on the accuracy of peripheral capillary oxygen saturation. Perhaps more important than blocking out ambient light is the need for meticulous attention to probe placement with precise opposition of the light source and detectors, as misalignment of the optical components invites interference from environmental light. This may be particularly difficult in critically ill, restless, diaphoretic, or active patients.
With regard to the use of these devices for diagnosis of sleep apnea, Hayes assigned the following rating:

D2 - For home sleep studies in patients younger than 18 years of age. This Rating reflects the lack of evidence regarding the impact on health outcomes or patient management, and the sparse and inconsistent evidence regarding the diagnostic accuracy of home sleep studies in the pediatric population, which does not allow for any predictions of impact on health outcomes.⁹

Nocturnal oximetry has been proposed as an abbreviated and low-cost testing modality for the diagnosis of obstructive sleep apnea syndrome (OSAS) in lieu of polysomnography. A systematic review found a consistent correlation between nocturnal SpO₂ drops to <90%, more than two clusters of desaturation events (≥4%) and oxyhemoglobin desaturation (≥4%) index (ODI4) at a rate of >2.2 episodes/h to be suggestive evidence of OSAS. At least three clusters of desaturation events, and at least three SpO₂ drops below 90% in a nocturnal oximetry recording are indicative of moderate-to-severe OSAS. An ODI₄ >2 episodes/h combined with OSAS symptoms also exhibits high positive predictive value for apnea-hypopnea index at a rate of >1 episode/h. The authors concluded that nocturnal oximetry is a valuable tool that can facilitate treatment decisions for OSAS when polysomnography is not available.¹⁰

Cochrane (2015) sought to examine the use of pulse oximeters to self-monitor asthma exacerbations at home to determine if their use as part of a personalized asthma action plan (PAAP) was safer and more effective than a PAAP alone. The authors found no studies and no evidence to support or refute the use of home pulse oximetry in self-management of asthma; and therefore made no recommendations about use of pulse oximetry as part of a PAAP.¹¹

A cohort trial of patients examined undiagnosed and untreated sleep-disordered breathing among patients with congestive heart failure (CHF). The authors concluded that the combined use of a symptom score questionnaire, the Epworth sleepiness scale, and overnight pulse oximetry was significantly more effective in identifying patients with sleep-disordered breathing than using the Epworth sleepiness scale alone (P <.05).¹²

The American Association for Respiratory Care (AARC) recommends that arterial blood gas values be compared to transcutaneous readings taken at the time of arterial sampling, in order to verify that transcutaneous values are accurate, and repeated periodically as dictated by the patient’s clinical condition.¹³

Hayes (2016) concluded that the evidence is insufficient to designate superiority of the Masimo pulse-oximetry device over the Nellcor (Covidien) product. The limited data suggests that both manufacturers have products that perform comparably. Decisions regarding pulse oximetry should consider ease of use, probe expense (reusable or single-use), compatibility with existing monitor platforms, and vendor support/training. There is insufficient evidence to support the use of Masimo’s addition of co-oximetry capabilities in critical clinical situations.¹⁴

Hayes noted that device interference may occur in the presence of multiple monitors, and measures to block or reduce the interference of light, motion, and electricity are in development. The prudent use of device rental or leasing may be advantageous as the products evolve in the near future.

**REGULATORY INFORMATION**

Kentucky – No legislative mandates were found for coverage of pulse oximetry in the home.
Indiana – No legislative mandates were found for coverage of pulse oximetry in the home.

Tennessee – No legislative mandates were found for coverage of pulse oximetry in the home.
Pulse oximeters are FDA cleared as Class II devices.

**COVERAGE DETAIL**

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, [http://www.cms.gov](http://www.cms.gov). Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<tbody>
<tr>
<td>94014</td>
<td>Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician review and interpretation</td>
<td>Not medically necessary and/or experimental/investigational</td>
</tr>
<tr>
<td>94015</td>
<td>Patient-initiated spirometric recording per 30-day period of time; recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis, and periodic recalibration)</td>
<td>Not medically necessary and/or experimental/investigational</td>
</tr>
<tr>
<td>94016</td>
<td>Patient-initiated spirometric recording per 30-day period of time; physician review and interpretation only</td>
<td>Not medically necessary and/or experimental/investigational</td>
</tr>
<tr>
<td>94760</td>
<td>Noninvasive ear or pulse oximetry for oxygen saturation; single determination</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>94761</td>
<td>Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (e.g., during exercise)</td>
<td>Medically necessary when criteria are met</td>
</tr>
<tr>
<td>94762</td>
<td>Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)</td>
<td>Not medically necessary and/or experimental/investigational</td>
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<tr>
<th>HCPC® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<tbody>
<tr>
<td>A4606</td>
<td>Oxygen probe for use with oximeter device, replacement</td>
<td>Medically necessary when criteria are met</td>
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### Pulse Oximetry for Home Use

**E0445** Oximeter device for measuring blood oxygen levels noninvasively

<table>
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<th>Modifier</th>
<th>Description</th>
<th>Coverage Information</th>
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<tr>
<td>RR</td>
<td>Rental (use the RR modifier when DME is to be rented)</td>
<td>Purchase is NOT medically necessary</td>
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</table>

**REFERENCES**


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**SEARCH TERMS**

Pulse oximeter
Arterial oxygen pressure
PaO2
Desaturation
Oxygenation