



November 18, 2008

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**Re: Formal Request for an NCD for Home Sleep Testing Devices That Diagnose Obstructive Sleep Apnea by Measuring the Peripheral Arterial Tone (PAT) Signal, Heart Rate, Blood Oxygen Saturation and Sleep Time**

Dear Drs. Phurrough and Jacques:

This letter and supporting documentation is a formal Track #1 request for a National Coverage Determination (NCD) on whether Home Sleep Testing (HST) devices<sup>1</sup> measuring the peripheral arterial tone (PAT) signal (a measure of sympathetic activation), heart rate, blood oxygen saturation, and sleep time are reasonable and necessary for the diagnosis of obstructive sleep apnea (OSA). An example of a device that measures all of these parameters is the Watch-PAT, which is manufactured by Itamar Ltd.<sup>2</sup> In this letter, HST devices that use the PAT signal

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<sup>1</sup> We have used the term home sleep testing for consistency with the CPAP NCD (240.4), however the term portable sleep testing provides a more accurate description of the devices at issue since the devices are used in sites of services other than beneficiaries' homes (e.g., inpatient hospital, skilled nursing facility, as well as sleep labs).

<sup>2</sup> The Watch-PAT family of home sleep testing devices are all based on the peripheral arterial tone (PAT) signal and includes these models of the device: 1) Watch-PAT 100, 2) Watch-Pat 100s, 3) Watch-Pat 100s-2, 4) Watch-Pat 200i, and 5) Watch-PAT 200s-2.

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along with heart rate, blood oxygen saturation, and sleep time to diagnose OSA will be referred to as “PAT HST devices.”

The Medicare Benefit Category for PAT HST devices is Diagnostic Tests (other) found at Social Security Act (SSA) §1861(s)(3).<sup>3</sup> We are requesting a new NCD as described below.

We request that the Centers for Medicare and Medicaid Services (CMS) determine that PAT HST devices are reasonable and necessary for the diagnosis of OSA and that prescribed treatments for OSA (e.g., CPAP, oral appliance therapy, surgery) are reasonable and necessary when OSA is diagnosed with a PAT HST device. We include the following in this cover letter: 1) a list of specific questions for CMS to consider in making its coverage determination; 2) specific language for the requested NCD; and 3) a request that CMS expedite the NCD process for this request by posting its proposed decision memorandum at the same time that it posts the request announcing the opening of the National Coverage Analysis (NCA). As attachments to this letter, we provide all of the supporting documentation required to make this a “Complete, Formal Initial Request for a National Coverage Determination” as described in the September 26, 2003, Notice on the Revised NCD Process. The attachments are organized in the order that the items are listed in that notice.<sup>4</sup>

## **I. Proposed Questions for the Watch-PAT NCA**

We request that in addition to answering the three questions posed below CMS make the following finding:

*Home sleep testing (HST) devices that measure, at minimum, the peripheral arterial tone (PAT) signal, heart rate, blood oxygen saturation, and sleep time (e.g., Watch-PAT) are a category of devices that are not identified by the American Academy of Sleep Medicine (AASM) classification system for sleep-apnea evaluation studies (Types I-IV).<sup>5</sup>*

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<sup>3</sup> See Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2) at 6 (“CMS considers diagnostic testing to be the appropriate coverage category for PSG and multichannel HST.”).

<sup>4</sup> See 68 Fed. Reg 55636-37.

<sup>5</sup> See Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. Sleep 1994; 17(4):378-392.

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*Therefore, HST PAT devices require a unique, independent classification (e.g., PAT-based HSTs). HST PAT devices use different sensors than Type II or Type III devices to provide valid data on AHI/RDI and sleep, which means that in clinical practice they provide information that is most comparable to a Type II device.*

*Question 1: Is the evidence adequate to determine that HST devices that measure, at minimum, the PAT signal, heart rate, blood oxygen saturation, and sleep time (e.g., Watch-PAT) calculate the Apnea-Hypopnea Index (AHI) and/or the Respiratory Disturbance Index (RDI) as accurately as PSG?*

*Question 2: Is the evidence adequate to determine that HST devices that measure, at minimum, the PAT signal, heart rate, blood oxygen saturation, and sleep time, when performed in conjunction with a clinical evaluation, are reasonable and necessary for the diagnosis of obstructive sleep apnea (OSA)?*

*Question 3: Is the evidence adequate to determine that treatment for OSA (e.g., CPAP) is medically necessary for patients with OSA that has been diagnosed with a clinical evaluation and a HST device that measures, at minimum, the PAT signal, heart rate, blood oxygen saturation, and sleep time?*

We have included Question 3 because we believe it was the intent of CMS in the CPAP NCD to require coverage of CPAP in patients with OSA who were diagnosed by clinical evaluation and use of a PAT HST. However, at the time this request is being submitted, the DME MAC policies implementing the CPAP NCD do not cover PAT HST devices. We believe that the DME MACs have misinterpreted the CPAP NCD. Therefore, it is critically important to assure that CMS address this issue directly through this NCD and then make, if necessary, technical corrections to the CPAP NCD to ensure that the two NCDs are consistent.

## **II. Proposed Watch-PAT NCD Language**

We provide draft language below for a new, stand alone NCD for HSTs that diagnose OSA by measuring the PAT signal, heart rate, blood oxygen saturation, and sleep time. Assuming CMS believes that it must make technical corrections to the CPAP NCD so that it is consistent with the HST NCD that we are requesting, we provide draft edits to the CPAP NCD in Exhibit A.

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The following text is suggested language for the new, stand alone NCD that we are requesting:

**Benefit Category**

Diagnostic Tests (other) -- (Social Security Act §1861(s)(3))

**Coverage Topic**

Home Sleep Tests (HSTs) That Diagnose Obstructive Sleep Apnea (OSA) by Measuring the Peripheral Arterial Tone (PAT) Signal, Heart Rate, Blood Oxygen Saturation, and Sleep Time

**Item/Service Description**

**A. General**

OSA is apnea or hypopnea caused by recurring interruption of breathing during sleep because of obstruction of the upper airways resulting in hypoxemia and in chronic lethargy during the day.

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. Apnea and hypopnea events can be measured accurately directly as well as indirectly through use of an HST device that measures PAT signal, heart rate, blood oxygen saturation.

The apnea hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The respiratory disturbance index (RDI) is equal to the average number of respiratory disturbances per hour. AHI and/or RDI can be accurately measured through use of an HST device that measures PAT signal, heart rate, blood oxygen saturation, and sleep time.

HST devices that measure, at minimum, the PAT signal, heart rate, blood oxygen saturation, and sleep time (e.g., Watch-PAT) are a category of devices that are not identified by the American Academy of Sleep Medicine (AASM) classification system established in 1994 for sleep-apnea evaluation studies (Types I-IV).<sup>6</sup> Therefore, HST PAT devices require a unique, independent

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<sup>6</sup> *Id.*

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classification (e.g., PAT-based HSTs). HST PAT devices use different sensors than Type II or Type III devices to provide valid data on AHI/RDI and sleep, which means that in clinical practice they provide information that is most comparable to a Type II device.

## **Indications and Limitations of Coverage**

### **B. Nationally Covered Indications**

Effective for claims with dates of service on and after \_\_\_\_\_, the Centers for Medicare & Medicaid Services (CMS) determines that HSTs that diagnose OSA by measuring the PAT signal, heart rate, blood oxygen saturation, and sleep time are considered reasonable and necessary for the diagnosis of OSA in adult patients because it calculates the AHI and/or the RDI as accurately as PSG. In addition, treatment for OSA (e.g., CPAP) is reasonable and necessary when OSA is diagnosed with a PAT HST device.

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### **III. Classification of PAT-based HST Devices**

In the Decision Memorandum for the second reconsideration of the CPAP NCD, CMS stated that it “consider[s] the Watch-PAT100 as a three channel Type IV device for the purposes of this decision.”<sup>7</sup> The description of PAT HST as a three channel Type IV device is incorrect because PAT HST devices are not identified by the AASM classification system for sleep apnea evaluation studies (Types I-IV)<sup>8</sup>. Furthermore, the description of PAT HST as a three channel Type IV device has resulted in an incorrect perception that the clinical information provided by PAT HST devices is less than that of Type II or Type III devices, when in fact, PAT HST devices provide clinical information most similar to Type II devices. PAT HST devices do not fit any of the AASM classes and require a unique, independent classification (e.g., PAT-based HSTs).

Statements about the Watch-PAT being a “three channel Type IV device” appear only in the Decision Memorandum and not in the actual CPAP NCD, and therefore CMS is not bound by such statements. Because “[a] decision memorandum is not an NCD,”<sup>9</sup> it would not be inconsistent with the CPAP NCD for CMS to conclude in this requested NCD that PAT-based HSTs are independently classified and are not three channel Type IV devices or any type of device within the AASM classification system for sleep-apnea evaluation studies (Types I-IV).

### **IV. NCD Process**

We request that CMS expedite the NCD process in this case by releasing its proposed decision memorandum at the same time that it opens the NCD by posting the NCA tracking sheet on its website along with the proposed decision memorandum and forgoing the first 30 day comment period that generally occurs between the posting of the tracking sheet and the posting of the proposed decision memorandum.

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<sup>7</sup> Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2) at 23.

<sup>8</sup> Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep* 1994; 17(4):378-392.

<sup>9</sup> Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55634, 55639 (September 26, 2003).

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We believe this is appropriate for a number of reasons:

a) The CPAP NCD has caused considerable confusion in the medical community and among local Medicare contractors over coverage of PAT HST, as reflected by LCDs that appear to be inconsistent with the NCD, and this confusion is undermining the intent and implementation of the CPAP NCD and possibly impairing beneficiary access to care;

b) CMS has already reviewed almost all of the available clinical evidence on this issue and the public has had multiple opportunities to comment;

c) CMS is permitted by law to expedite the NCD process because it need only offer one 30 day comment period, and it has done so on other occasions when there was an important programmatic need to do so; and

d) There are important programmatic reasons to expedite the NCD process in this case.

A. Confusion Surrounding the CPAP NCD

There is significant urgency to expedite the NCD process in this case given the confusion created by the implementation of the NCD for CPAP Therapy for OSA dated March 13, 2008 (240.4). This confusion has occurred on at least two levels. First, much of the medical community thought, based on the Technology Assessment performed in connection with the NCA and the lengthy discussion in the Decision Memorandum of the clinical evidence showing that HST accurately diagnoses OSA, that the CPAP NCD would include a finding that HST was reasonable and necessary in the diagnosis of OSA. Unfortunately, this did not happen and, in fact, the only effect the CPAP NCD had on coverage of HST was to change the previous national non-coverage of HST to coverage at Contractor discretion. This change has resulted in LCDs concerning HST that are inconsistent with the CPAP NCD and that have caused great confusion concerning which HST devices are now covered at the local level. For example, the NCD provides coverage for CPAP when OSA is diagnosed with a clinical evaluation and a positive unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.” Yet, the LCD by Medicare Contractor Pinnacle Business Solutions, Inc. describes unattended HST devices as follows:

Unattended home sleep monitoring devices of Type II, III, and IV (3 channel. At a minimum, HST/PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and

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oximetric biosensors conventionally used for in-laboratory PSG should be used in HST/PM) are only indicated to qualify an adult patient with Obstructive Sleep Apnea for a 12-week trial of CPAP. (NCD 240.4)<sup>10</sup>

This policy limits HST devices to only those utilizing measurement of airflow and respiratory effort and other specific sensors, and excludes from coverage PAT HST devices. None of the restrictions listed in the above-quoted paragraph from the Pinnacle LCD are required by the CPAP NCD and appear to be inconsistent with the CPAP Decision Memorandum that favorably reviewed PAT HST devices (as discussed further below).

Second, confusion was created because the language from the Decision Memorandum that specifically acknowledged the clinical utility of PAT HST devices was omitted<sup>11</sup> from the Program Transmittal that contained implementation instructions to Medicare Contractors. The omitted language has resulted in the recent publication of Local Coverage Determinations (LCDs)<sup>12</sup> by the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) that appear to be inconsistent with the NCD because they do not cover CPAP for patients in whom OSA has been diagnosed by a PAT HST device.

Third, we believe that the suggestion in the CPAP Decision Memorandum that HST devices that measure a PAT signal are three-channel Type IV HSTs is an additional source of confusion, as it may suggest that PAT HST are a sub-set of Type IV devices which are generally defined as devices measuring 1 or 2 parameters and are not sufficient to establish an accurate diagnosis of OSA. To reiterate, HST devices that measure, at minimum, the PAT signal, heart rate, blood oxygen saturation and sleep time (e.g., Watch-PAT) are a unique type of HST device and do not correspond with any of the four types of HSTs (Types I-IV) established in 1994 by the AASM. Specifically, PAT HST devices measures at least four physiological parameters.

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<sup>10</sup> Medicare Part B Local Coverage Determination, Outpatient Sleep Studies, Determination number AC-03-030.

<sup>11</sup> See § IV.B. below for a discussion of CMS's evaluation and conclusions concerning the Watch-PAT, an HST that measures PAT.

<sup>12</sup> See NHIC's LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11528); See also NGS's LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L27230), CIGNA's LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11518), and Noridian's LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L171).



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Furthermore, unlike Type III and Type IV devices that do not provide any sleep information, PAT HST devices provide extensive data on sleep time.

B. CMS Already Reviewed the Evidence on Use of HST to Diagnose OSA

CMS thoroughly reviewed the evidence on using HST for diagnosis of OSA on several occasions, and the public has had multiple opportunities to comment on the entire range of related issues throughout CMS's long process of establishing coverage for CPAP which has included two reconsiderations.

CMS first opened an NCD on CPAP on June 4, 2001. This NCD, which included two public comment periods, was issued on October 30, 2001. The first reconsideration of the CPAP policy was posted on April 8, 2004, for the express purpose of "reassess[ing] the national coverage determination for diagnosis and treatment of obstructive sleep apnea (OSA) to include multichannel home sleep testing as an alternative to polysomnography (PSG)."<sup>13</sup> This first reconsideration of the CPAP NCD included a Technology Assessment performed by the Agency for Healthcare Research and Quality (AHRQ) titled *Effectiveness of Portable Monitoring Devices for Diagnosing Obstructive Sleep Apnea: Update of a Systematic Review* and a MedCAC meeting in addition to two separate 30-day comment periods that occurred before and after the release of the proposed decision memorandum. This first reconsideration of the CPAP NCD focused specifically on the issue of whether to expand the coverage of CPAP to include patients diagnosed with OSA using HST. The NCD resulting from the first reconsideration was issued on April 4, 2005.

Most recently, a second reconsideration was opened on March 14, 2007. Like the first reconsideration, the second reconsideration was requested for the purpose of "reassess[ing] the National Coverage Determination (NCD) for diagnosis and treatment of obstructive sleep apnea (OSA) to include home sleep testing as an alternative to polysomnography (PSG) by physicians licensed to practice medicine."<sup>14</sup> Again, CMS itself reviewed all of the evidence on HST for OSA, requested that AHRQ perform two more technology assessments (which were published in August and September 2007) and held another MedCAC meeting. The technology

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<sup>13</sup> Request letter for the first reconsideration of the CPAP NCD, from Terence M. Davidson, MD to Steve Phurrough, MD, MPA, dated January 29, 2004.

<sup>14</sup> Request letter for the first reconsideration of the CPAP NCD, from David R. Nielsen, MD, FACS to Steve Phurrough, MD, MPA, dated January 2, 2007.

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assessments were titled 1) *Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome* (August 8, 2007) and 2) *Obstructive Sleep Apnea-Hypopnea Syndrome: modeling different diagnostic strategies* (December 4, 2007). The specific aims of the first technology assessment demonstrate that AHRQ provided CMS with a comprehensive assessment of the diagnosis of OSA using HST and that no further review of the evidence is required before posting of a proposed decision memo.<sup>15</sup>

Not only has the public been afforded multiple comment periods as part of the initial NCD and the two reconsiderations (including both before and after the release of the proposed decision memoranda and at the two MedCAC meetings), but CMS specifically reviewed the evidence supporting the use of PAT HST and responded to comments on PAT HST in the Decision Memorandum for the second reconsideration.<sup>16</sup> Specifically, CMS evaluated the evidence for PAT HST devices (i.e., the Watch-PAT) and after an extensive review, CMS agreed that: “the Watch-PAT100 is a useful diagnostic tool and should not be distinguished from other HST devices [that are used in the diagnosis of OSA].”<sup>17</sup> CMS also concluded the following regarding the Watch-PAT 100:

CMS separately reviewed evidence on the use of the Watch-PAT100 device (see above), a multichannel device that measures PAT. The conclusions that can be confidently drawn from the evidence, while mildly constrained by methodologic limitations (sample and subject selection, sample size, non-consecutivity of subjects, confounders not accounted for, and combining results of different types of patients in analysis), are of similar strength as that available for many of the type IV devices in the TA and, therefore, we consider the Watch-PAT100 as a three channel Type IV device for the purposes of this decision.<sup>18</sup>

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<sup>15</sup> This technology assessment provided a comprehensive review and analysis of HST. See the list of the specific aims of the technology assessment on pages 16-17 of the assessment.

<sup>16</sup> See Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2) at 13-15 for a thorough summary of the published peer-reviewed evidence on the Watch-PAT device.

<sup>17</sup> *Id.* at 19.

<sup>18</sup> *Id.* at 23 (emphasis added).

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These findings combined with the statement from the CPAP NCD that a covered sleep test includes an “unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels,” at a minimum implies that it is the intent of CMS that PAT HSTs (e.g., the Watch-PAT) are medically reasonable and necessary for the diagnosis of OSA (in combination with an appropriate clinical evaluation) and that CMS will pay for CPAP when OSA is diagnosed using PAT HST under the CPAP NCD.

Unfortunately, while this language appears clear on its face, it has caused confusion in the medical community and among Medicare Contractors, because it insufficiently communicated that CMS had evaluated the evidence and concluded that the Watch-PAT is a covered HST device. This confusion arose in part because CMS described the Watch-PAT as a three-channel Type IV device instead of as a unique type of HST device that accurately establishes AHI and/or RDI and provides data on sleep time.

Further, there has been only one peer-reviewed article published since the CPAP NCD was issued in March 2008. It is enclosed with this request and its findings further establish the efficacy of PAT HST in diagnosing OSA and that CPAP treatment outcomes are for patients whose OSA was diagnosed with PSG or with PAT HST. Therefore, CMS already has reviewed the evidence and performed the analysis that will form the basis of a proposed decision memorandum on PAT HST devices, and concluded that PAT HST devices (specifically referring to the Watch-PAT) are reasonable and necessary for the diagnosis of OSA. Further, there has been ample opportunity on many occasions for the public to comment on the HSTs, and, in fact, CMS responded to public comments on this specific issue so it would be appropriate for CMS to release the proposed decision memo on the date that it opens the NCA with a single public comment period following the posting of the proposed decision memorandum.<sup>19</sup>

### C. CMS Has the Statutory Authority to Expedite the NCD Process

CMS has posted its proposed decision memorandum at the same time that it posted the tracking sheet in other NCAs, e.g., the second reconsideration of the clinical trial policy.<sup>20</sup> It did

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<sup>19</sup> *Id.* at 18-21 (for comments and CMS’s responses) on the Second reconsideration for CPAP Therapy for OSA.

<sup>20</sup> *See* NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R2), in which the formal request was accepted and the review initiated on July 19, 2007, and the proposed decision memorandum was also released on July 19, 2007. At the beginning of this tracking sheet CMS explains its rationale for releasing the proposed decision memorandum on the same date that it opened the NCD.

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so in the case of the Reconsideration of the Clinical Trial Policy because there had been ample opportunity for public comment through a prior reconsideration of the policy and because of the strong interest in an expeditious resolution of the policy given the broad applicability of the policy and the need to “clarify ambiguities” associated with the NCD that resulted from the first reconsideration of the clinical trial policy.

There are no statutory or regulatory requirements that CMS have *two* 30-day comments periods (i.e., one at the time of the posting of the tracking sheet and another after the release of the proposed decision memorandum). The statutory requirement specifying the process for public comment in national coverage determinations is § 1862(l)(3), which states the following:

(3) Process for public comment in national coverage determinations.—

(A) Period for proposed decision.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare and Medicaid Services or other appropriate means.

(B) 30-day period for public comment.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-day period for final decision.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

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(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

This requirement calls for only a *single* 30-day comment period after the posting of the proposed decision memorandum. The statutory requirement for a comment period was established because it was felt that the past NCD process was not sufficiently transparent. In this case, the process has been extraordinarily transparent and this issue has been the subject of public comment on numerous occasions. Furthermore, the statute specifies that the final decision shall be made “[n]ot later than 60 days after the conclusion of the 30-day period.” Therefore, CMS could issue the final decision memo any time between one and 60 days after the 30-day comment period ended.

CMS guidance on the “Factors CMS Considers in Opening a National Coverage Determination” describes the comment process that it usually uses for NCDs:

Once the request is considered “received,” we post the request on our web site under our list of pending coverage issues. Posting of the tracking sheets permits interested individuals to participate in and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be additional opportunities for public participation and submission of additional evidence (such as the initial 30-day comment period and 30-day comment period on the draft NCD).<sup>21</sup>

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<sup>21</sup> Guidance for the Public, Industry and CMS Staff, Factors CMS Considers in Opening a National Coverage Determination, issued April 11, 2006 at 8.

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The purpose of this guidance was to discuss transparency and the public's ability to comment. This guidance notwithstanding, there is no statutory or regulatory requirement that mandates these two separate 30-day comment periods. As previously described, there have been extensive comment periods for HST over two reconsiderations of the CPAP NCD. CMS provides for two comment periods during an NCA but is not required to and elected to have only one 30-day comment period in the second reconsideration of the clinical trial policy which was opened *after* the publication of the guidance document language quoted above.

We also note that in posting the second reconsideration of its Clinical Trial Policy in an expedited manner, CMS cited the need to "clarify ambiguities" in that policy that were causing confusion in the clinical trial community. The ambiguities cited as a need for reconsideration of that policy are very similar to the ambiguities here because they were related to providers not understanding when and how certain items and services were covered under the policy. In the case of the CPAP NCD, there are ambiguities as to whether or not HST coverage is part of the NCD and ambiguities in the definition of HST making it unclear when Medicare will pay for CPAP if the diagnosis of OSA is made using an HST. These ambiguities are exacerbated by CMS describing PAT HST devices as three channel Type IV devices when PAT HSTs are not Type IV devices.

D. Expediting the NCD Process in this Case Would Serve an Important Programmatic Objective

The CPAP NCD was an important step in assuring that Medicare beneficiaries have access to CPAP when diagnosed with OSA using home testing. The CPAP NCD intended CPAP to be covered for OSA diagnosed with different types of HST, including PAT HST. Unfortunately, because the CPAP NCD did not explicitly cover HST and did not clearly define which HST devices were medically reasonable and necessary, the DME MAC and Part A/B Contractor LCDs implementing the NCD are not consistent and have created confusion in the medical community, especially as it relates to PAT HST. This confusion is resulting in physicians being unsure as to whether or not PAT HST is covered and payable, which could result in overall less diagnosis and treatment of OSA to eligible beneficiaries, and/or the continued use of much more costly alternative sleep tests.

We believe that our suggested approach is consistent with the Medicare statute, consistent with CMS past practices, is the most efficient and least burdensome approach to this NCD request and is consistent with the need for Medicare beneficiaries to have access to devices cleared by FDA that can diagnose OSA accurately and in a timely manner and allow initiation of

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treatment as quickly as possible, all of which are consistent with the intent of the NCD. Given the urgency under these circumstances and considering the extensive evidence review already performed by the Coverage and Analysis Group on evidence supporting the use of PAT HST for diagnosing OSA, posting the proposed decision memorandum at the time that the NCD is opened will avoid unnecessary delay, especially considering that prompt resolution of the confusion surrounding the CPAP NCD is highly desirable for all stakeholders and CMS.

The following pages and Exhibits contain the necessary supporting documentation for this NCD request. Thank you for your time and prompt attention to this request.

Sincerely,

A handwritten signature in cursive script, appearing to read "I. Schreiber", enclosed within a rectangular border.

Israel Schreiber  
On behalf of Itamar Medical

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## **SUPPORTING DOCUMENTATION**

### **I. Full and Complete Description of the Service and Specific, Detailed Description of the Proposed Use of the Service**

The Watch-PAT is a unique technology for the home diagnosis and treatment assessment of OSA for patients who will respond clinically to the treatment of OSA (e.g., CPAP). The Watch-PAT measures the peripheral arterial tone (PAT) signal, a validated surrogate measure of sympathetic activation that is associated with apneic events and respiratory effort related arousals. The Watch-PAT gives all OSA indices i.e., AHI (Apnea Hypopnea Index), RDI (Respiratory Disturbances Index) and ODI (Oxygen Desaturation Index). In addition, the Watch-PAT provides extensive additional information, including heart rate, total sleep time, and sleep stages (including REM, Deep Sleep and Light Sleep). This information enables the accurate assessment of the presence and severity of OSA and its effect on sleep architecture and sleep quality.

### **II. Compilation of the Supporting Medical and Scientific Information Currently Available that Measures the Medical Benefits of the Service**

The peer-reviewed publications on the Watch-PAT are listed as follows and full-text reprints of these ten articles are included in Exhibit B. A complete list of publications and abstracts on the Watch-PAT is attached as Exhibit C.

1. Pillar G, Bar A, Shlitner A, Schnall RP, Sheffy J, Lavie P. Autonomic Arousal Index (AAI): An Automated Detection based on Peripheral Arterial Tonometry. *SLEEP* 2002; 25(5):543-549.
2. Bar A, Pillar G, Dvir I, Sheffy J, Schnall RP, Lavie P. Evaluation of a Portable Device Based on Peripheral Arterial Tone for Unattended Home Sleep Studies. *Chest* 2003; 123(3): 695-703.
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### **III. Summaries of FDA Clearances for the Watch-PAT Devices**

Attached as Exhibit D are the 510(k) Summaries of Safety and Effectiveness information for the Watch-PAT 100, Watch-Pat 100s, Watch-Pat 100s-2, Watch-Pat 200i, and the Watch-PAT 200s-2.

### **IV. Explanation of the Design, Purpose, and Method of Using the Watch-PAT**

The Watch-PAT is a patient-worn, self-contained device used in the patient's home. It is a non-invasive device worn on the hand and wrist and is attached to a number of physiological sensors, including a non-invasive finger-mounted pneu-optical probe to measure the peripheral arterial tone (PAT) signal.

The Watch-PAT measures the peripheral arterial tone (PAT) signal, a validated surrogate measure of sympathetic activation that is associated with apneic events and respiratory effort related arousals. The Watch-PAT gives all OSA indices i.e., AHI (Apnea Hypopnea Index), RDI (Respiratory Disturbances Index) and ODI (Oxygen Desaturation Index). In addition, the Watch-PAT provides extensive additional information, including heart rate, total sleep time, and sleep stages (including REM, Deep Sleep and Light Sleep). This information enables the accurate assessment of the presence and severity of OSA and its effect on sleep architecture and sleep quality.

The recorded PAT signals are stored in a removable memory card in the device that is downloaded to a computer for subsequent analysis and report generation. Like most other HST devices and polysomnography (PSG) systems, the Watch-PAT provides automatic analysis of its data as well as full disclosure of raw data that enables physicians to over read the automatic analysis and modify it manually. Attached as Exhibit E is additional information describing the PAT signal and its application in accurately detecting disturbances of airflow during sleep.

### **V. Statement from the Requestor Regarding the Evidence for the Watch-PAT**

#### **A. Explanation of the Relevance of the Evidence Selected**

All of the thirteen published peer-reviewed articles listed above in section II evaluate the Watch-PAT in the diagnosis of OSA, sleep/wake states and sleep stages. CMS reviewed and analyzed six of the thirteen articles in its recent CPAP Decision Memorandum. The other seven

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articles are included because they are published, peer-reviewed studies evaluating the Watch-PAT in the diagnosis of OSA that were not included in CMS's evidence review in the CPAP Decision Memorandum.

**B. Rationale of How the Evidence Selected Demonstrates the Medical Benefits for the Target Medicare Population**

The medical benefit of the Watch-PAT is supported by thirteen peer-reviewed studies (listed above in section II and attached as Exhibit B), six of which have already been thoroughly reviewed by CMS and summarized in the CPAP Decision Memorandum. The other seven articles are summarized as follows:

- Pittman et. al (2006) assessed the accuracy of the Watch-PAT (WP) in detecting residual episodes of sleep disordered breathing (SDB) during CPAP therapy.<sup>22</sup> Seventy patients using CPAP for at least three months were evaluated using WP and PSG simultaneously in three different sleep labs. For  $RDI \geq 15$ , the area under the curve was 0.95, leading the authors to conclude that WP "accurately identified participants with moderate-severe SDB while using CPAP."
- Pang et. al (2007) conducted an independent study of 37 consecutively selected patients referred to a sleep lab for suspected OSA.<sup>23</sup> Each patient's sleep was recorded using WP and laboratory PSG simultaneously during the same night in the sleep lab. The study found WP had high correlation, sensitivity, and specificity with PSG (0.93, 0.96 and 0.7996, respectively). The study authors concluded that, in addition to demonstrating a high correlation with PSG, WP is "small, lightweight, inexpensive, reliable, accurate, easy to use, and safe."

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<sup>22</sup> Pittman SD et al., Follow-up assessment of CPAP efficacy in patients with obstructive sleep apnea using an ambulatory device based on peripheral arterial tonometry. *Sleep Breath* (2006) 10: 123-131.

<sup>23</sup> Pang KP et al. A comparison of polysomnography and the WatchPAT in the diagnosis of obstructive sleep apnea. *Otolaryngology-Head and Neck Surgery* (2007) 137, 665-668.

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- Townsend et. al (2007) performed one of the more extensive studies that evaluated treatment outcomes in patients diagnosed with an HST device and PSG, respectively.<sup>24</sup> This community-based study followed 103 patients who were randomized to either home diagnosis using WP or in-lab diagnosis using PSG. The study evaluated the CPAP compliance and quality of life measures three months and six months following CPAP initiation. All measures between the two groups were comparable, including CPAP compliance with  $5.4 \pm 1.8$  hours per night for the WP group vs.  $5.5 \pm 1.7$  hours per night for the PSG group at six months.
- Berry et al. (2008) did a randomized parallel group study of 106 patients with daytime sleepiness at the Veterans Administration Medical Center that compared a clinical pathway using the Watch-PAT 100 for diagnosis of Obstructive Sleep Apnea (OSA) and unattended auto-titrating positive airway pressure (APAP) to select an effective continuous positive airway pressure (CPAP) with another pathway using polysomnography (PSG) for diagnosis and treatment of OSA.<sup>25</sup> At a clinic visit 6 weeks after starting CPAP, 40 patients in the Watch-PAT-APAP group (78.4% of those with OSA and 88.8% started on CPAP) and 39 in the PSG arm (81% of those with OSA and 90.6% of those started on CPAP) were using CPAP treatment ( $p=NS$ ). The mean nightly adherence (Watch-PAT-APAP:  $5.20 \pm 0.3$  versus PSG  $5.25 \pm 0.4$  hours/night), decrease in Epworth sleepiness scale ( $-6.5 \pm 0.7$  versus  $-6.97 \pm 0.73$ ), improvement in the global Functional Outcome of Sleep Questionnaire score ( $3.1 \pm 0.05$  versus  $3.31 \pm 0.52$ ), and CPAP satisfaction did not differ between the groups. The investigators concluded that “the clinical pathway utilizing the Watch-PAT and APAP titration resulted in similar CPAP adherence and clinical outcomes as one using PSG.”
- Hedner *et al* (2004) validated the wake/sleep detection of the Watch-PAT in 228 OSA patients and normal volunteers in a three sites multi-center study – Boston (PI Dr. D White), Gothenburg ( PI Dr. J Hedner) and Haifa ( PI Dr. G Pillar). All subjects underwent a simultaneous Watch-PAT and PSG recording that were later compared on an epoch-by-epoch base( standard 30sec epochs) . The agreement between Watch-PAT and PSG ranged

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<sup>24</sup> Townsend D, Sharma A, Brauer E, Scattarelli D, et. al. Assessing Efficacy, Outcomes, and Cost Savings for Patients with Obstructive Sleep Apnea Using Two Diagnostic and Treatment Strategies. *Sleep Diagnosis and Therapy* 2007; 1(7): 1-8.

<sup>25</sup> Berry RB, Hill G, Thompson L, McLaurin V, Randall M. Portable Monitoring and Auto-Titration versus Polysomnography for the Diagnosis and Treatment of Sleep Apnea. *Sleep* 2008;31:1423-1431.

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from 86% in normal volunteers to 86%, 84% and 80% in mild, moderate and severe OSA patients. The authors concluded that "This simple method for assessment of total sleep time may provide a useful tool for the accurate quantification of obstructive sleep apnea in the home environment."

- Herscovici *et al* (2007) described and validated the Watch-PAT algorithms for the detection of REM / Non-REM sleep. Subjects were recorded simultaneously with PSG and Watch-PAT and validation was performed on 30 subjects . An epoch-by-epoch agreement of 90% for REM stage detection was reported.
- Bresler *et al* (2008) described and validated the Watch-PAT algorithms for the detection of Deep / Light Sleep stages. Subjects were recorded simultaneously with PSG and Watch-PAT and validation was performed on 44 subjects . An epoch-by-epoch agreement of 80% for Deep and Light Sleep stages detection was reported.

### **C. Information that Examines the Magnitude of the Medical Benefit**

The collective strength of the thirteen published, peer-reviewed studies for the Watch-PAT supports the conclusion that the Watch-PAT accurately and reliably diagnoses OSA, and, therefore, is properly considered reasonable and necessary for the diagnosis of OSA.

The evidence for the Watch-PAT is substantial in both quantity and quality. In fact, AHRQ considered the Watch-PAT studies to be high quality, especially relative to studies performed using other sleep testing devices. The Watch-PAT was the only device with three studies (out of the six reviewed initially by CMS) that received a data quality grade of B in the AHRQ Technology Assessment on the Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome (Pillar 2003, Ayas 2003, and Pittman 2003).

When CMS reviewed only six of the thirteen peer-reviewed studies as a part of the CPAP NCD, it concluded that the Watch-PAT was a covered HST for the diagnosis of OSA. The addition of the seven additional published, peer-reviewed studies (that were not reviewed by CMS in the CPAP Decision Memorandum) further demonstrating the accuracy of the Watch-PAT as compared to PSG in the diagnosis of OSA provides additional confirmation of CMS's original conclusion that the Watch-PAT accurately diagnoses OSA, and, therefore, should be covered for this indication.

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**D. Reasoning for How Coverage of the Watch-PAT Will Help Improve the Medical Benefit to the Target Medicare Population**

The Watch-PAT provides a new diagnostic and treatment assessment tool for the diagnosis and medical management of OSA. The Watch-PAT is proven through thirteen peer-reviewed published studies to be comparable to PSG in diagnosing OSA, sleep/wake states and sleep stages and therefore is a highly accurate diagnostic modality for OSA. The Watch-PAT is designed to fulfill the unmet need for an ambulatory, reliable, patient friendly diagnostic evaluation tool that is accessible to the great number of OSA sufferers, and to the equally important need for a cost effective means for follow up of treated patients. The Watch-PAT provides greater simplicity and flexibility in the diagnosis of OSA without compromising any of the accuracy and precision associated with other, more time-honored traditional methods and while providing additional important clinical data.

**VI. Description of Any Clinical Trials or Studies Underway Involving the Watch-PAT**

A large multi-center study is now being analyzed and a paper is in process. The study further validates the efficacy of the Watch-PAT when compared to PSG in the detection of sleep stages in OSA and normal subjects, overall 228 patients, in Boston (PI Dr. David White) ), Gothenburg ( PI Dr. Jan Hedner) and Haifa ( PI Dr. G. Pillar)

**VII. Information on the FDA Regulatory Status of the Watch-PAT**

All of the Watch-PAT HST devices have been cleared by the FDA through the 501(k) process. The Summaries of Safety and Effectiveness and the FDA clearance letters for each of the Watch-PAT devices are included as Exhibit D.

**VIII. Predicate Devices for the Watch-PAT devices**

- A. Watch-PAT 100 is substantially equivalent to the Mesam IV recorder and the Embla (Ferguson Medical).
- B. Watch-PAT 100s is substantially equivalent to the Watch-PAT 100 and Oxford Biosignal's BioSleep (Oxford Biosignal's Ltd.).
- C. Watch-PAT 100s-2 is substantially equivalent to the Watch-PAT 100s, Oxford Biosignal's BioSleep, Silent Night II (Sleep Solutions, Inc.), and Embla.

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- D. Watch-PAT 200 is substantially equivalent to the Watch-PAT 100s.
- E. Watch-PAT 200s-2 is substantially equivalent to the Watch-PAT 100s-2 and the Watch-PAT 200.

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## **Exhibit A**

### **CPAP NCD with Technical Correction (highlighted)**

#### **A. General**

Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

The apnea hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The respiratory disturbance index (RDI) is equal to the average number of respiratory disturbances per hour.

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. Apnea and hypopnea events can be measured accurately directly or indirectly through use of an HST device that measures PAT signal, heart rate, blood oxygen saturation.

The AHI and/or RDI may be measured by polysomnography (PSG) in a facility-based sleep study laboratory, or by a Type II home sleep test (HST) monitor, a Type III HST monitor, a Type IV HST monitor measuring at least 3 channels or a HST monitor that measures, at minimum, the peripheral arterial tone (PAT) signal, heart rate, blood oxygen saturation, and sleep time (e.g., Watch-PAT)

(i) Indications and Limitations of Coverage

#### **B. Nationally Covered Indications**

Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as



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subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.

2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
  - a. attended PSG performed in a sleep laboratory; or
  - b. unattended HST with a Type II home sleep monitoring device; or
  - c. unattended HST with a Type III home sleep monitoring device; or
  - d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.
  - e. unattended HST that measures, at minimum, the peripheral arterial tone (PAT) signal, heart rate, blood oxygen saturation, and sleep time.
4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:
  - a. AHI or RDI greater than or equal to 15 events per hour, or
  - b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

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6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.

7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. Apnea and hypopnea events can be measured accurately directly or indirectly through use of an HST device that measures PAT signal, heart rate, blood oxygen saturation.

8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions

a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?

b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

The study must meet the following additional standards:

c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

e. The research study does not unjustifiably duplicate existing studies.

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- f. The research study design is appropriate to answer the research question being asked in the study.
- g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
- i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
- j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
- k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- l. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
- m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the

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retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.