

February 8, 2024

VIA ELECTRONIC SUBMISSION

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Centers for Medicare & Medicaid Services

Mail Stop: C4-01-26

7500 Security Blvd.

Baltimore, Maryland 21244

RE: Potentially Misvalued Code Nomination for CPT code 95800

Dear Administrator Brooks-LaSure:

In accordance with the Centers for Medicare & Medicaid Services' (CMS') public nomination process for potentially misvalued codes, ZOLL Itamar (Itamar), a manufacturer and distributor of home sleep apnea testing (HSAT) devices, respectfully submits this nomination of potentially misvalued CPT code 95800¹ for the calendar year (CY) 2025 Medicare Physician Fee Schedule (PFS) rulemaking cycle.

As discussed in greater detail below, Itamar believes that CPT code 95800 is misvalued because clinical practice changes support the conclusion that the "typical procedure" reported with code 95800 utilizes disposable HSAT technology, such as the WatchPAT One device, rather than the reusable equipment currently included in the procedure's direct practice expense (PE) inputs. This misalignment between current medical practice and the PE inputs for CPT 95800 has resulted in inaccurate direct practice expenses for HSAT reported with code 95800 and created access challenges for Medicare beneficiaries, particularly in rural and remote areas. Accordingly, we request that CMS update the direct PE supply and equipment inputs for CPT 95800 to reflect the typical procedure's use with disposable HSAT technology. Specifically, we believe that the most accurate PE adjustments for code 95800 would:

1. **DELETE** equipment code EQ335 (reusable WatchPAT 200 unit), equipment code EQ336 (oximetry and airflow device), and supply code SD263 (WatchPAT probes used with reusable WatchPAT unit); and
2. **ADD** supply code SD362 (the WatchPAT ONE device) as a replacement for the deleted items.

¹ Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time.



I. WATCHPAT ONE BACKGROUND

The WatchPAT is a wrist-mounted device that allows sleep testing in the comfort of the patient's own home. Using Peripheral Arterial Tonometry (PAT) technology, the WatchPAT enables the non-invasive recording, measurement and analysis of the biological PAT signal, which measures changes in a patient's pulsatile arterial volume, providing a "window" to the cardiovascular system and the sympathetic branch of the autonomic nervous system. Home sleep tests performed with WatchPAT devices are typically reported with code 95800.

The WatchPAT product line includes the reusable WatchPAT 200 and WatchPAT 300, as well as the single-use WatchPAT ONE device. Like the other WatchPAT products, the WatchPAT ONE measures seven (7) channels (PAT signal, heart rate, oximetry, actigraphy, body position, snoring, and chest motion) and offers the same accuracy as the reusable WatchPAT products, but is entirely disposable. The cloud-based solution available through the WatchPAT ONE provides clinicians with immediate access to sleep data and study results, without the need to wait for the return of the reusable capital equipment to download the study data, thus allowing fast diagnosis and treatment. This configuration also enables physicians to extend care to rural populations that may not otherwise receive sleep testing services and reduces potential reinfection risk from reusable HSATs.

Similar to other reusable HSAT services reliant on PAT technology, the single-use WatchPAT One service is currently reported using CPT code 95800. Although the physician work for the service is the same for disposable and reusable HSATs, the practice expenses associated with single-use, disposable HSATs are different from those associated with reusable tests. For instance, while eliminating the cost for reusable equipment, disposable HSAT services involve higher costs for single-use supplies. As discussed below, these disparities in the equipment and supply costs for HSATs performed with disposable versus reusable devices result in underpayment to physicians (who purchase the device) when HSAT services using the disposable WatchPAT ONE are reported with CPT 95800.

II. CPT 95800: HISTORICAL VALUATION AND CLINICAL CHANGES

Valuation for CPT 95800 was last reviewed by CMS in the CY 2019 PFS Final Rule, when CMS finalized the existing work and direct PE inputs for three HSAT codes (CPT codes 95800, 95801, and 95806).² The existing inputs are based on a survey and recommendations from the April 2017 meeting of the American Medical Association (AMA) Relative Value System Update Committee (RUC), which adopted without modification the direct practice expense input recommendations of the specialty societies.³

² 83 Fed. Reg. 59,452, 59,568 (Nov. 23, 2018).

³ See April 2017 RUC Meeting Minutes at 51–52, <https://www.ama-assn.org/system/files/2018-11/6-april-2017-ruc-meeting-minutes.pdf>; see also AMA/Specialty Society Update Process Practice Expense Summary of Recommendation (SoR) Non Facility Direct Practice Expense (PE) Inputs (revised Apr. 27, 2017), <https://www.ama-assn.org/system/files/2018-11/3-may-2017-ruc-recommendations-final.pdf> [PDF page 2500–2506].



The CY 2024 supply and equipment inputs for CPT 95800 are shown below.⁴

CURRENT SUPPLY INPUTS (CY 2024 PFS FINAL RULE)					
CPT	Category	Supply Code	Description	Price	Quantity
95800	Accessory, Procedure	SD263	WatchPAT pneumo-opt slp probes	73.32	1
95800	Wound Care, Dressings	SG005	adhesive remover, liquid (Detachol) (0.67ml uou)	2.4	1
95800	Wound Care, Dressings	SG078	tape, surgical occlusive 1in (Blenderm)	0.007	8
95800	Pharmacy, NonRx	SJ053	swab-pad, alcohol	0.04	5
95800	Office Supply, Grocery	SK057	paper, laser printing (each sheet)	0.02	2
95800	Infection Control	SM021	sanitizing cloth-wipe (patient)	0.07	2
95800	Infection Control	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	0.07	2

CURRENT EQUIPMENT INPUTS (CY 2024 PFS FINAL RULE)					
CPT	Category	Equip Code	Description	Price	Equip Cost Per Minute
95800	OTHER EQUIPMENT	EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	1,237.5	4.707
95800	OTHER EQUIPMENT	EQ336	Oximetry and Airflow Device	1,195	4.545

In the time since these direct PE values were established for CPT 95800, there have been significant changes in the technologies available to perform HSAT services, as well as in clinical practice. For example, testing volume has shifted away from traditional airflow-based tests, while PAT-based (non-airflow) test volume grows. In addition, and as CMS recognizes, the COVID-19 public health emergency (PHE) changed the practice of medicine in every specialty, including sleep medicine. In-center sleep testing services like polysomnography (PSG) declined through the pandemic due to viral transmission concerns, while home sleep testing services have increased in importance to the diagnosis of sleep apnea.

Even within home sleep testing, the pandemic dramatically altered the delivery of HSAT services, with many sleep physicians transitioning to single-use, disposable sleep tests as an alternative to the reusable testing equipment that is shipped from patient-to-patient after post-use cleaning. Internal sales data suggests that disposable HSAT devices represented nearly 50% of

⁴ See CY 2024 PFS Final Rule Direct PE Inputs-Updated 12/19/2023, available at <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f>.



the devices used to perform code 95800 in 2023, and the trend strongly supports the conclusion that more than 50% of code 95800 services will use disposable devices in 2024 and 2025. This shift was initially driven in large part by concerns related to COVID-19 transmission and a higher degree of cleaning required between patients, as well as the recommendation of the leading sleep medicine society, the American Academy of Sleep Medicine (AASM), that “[u]sing single-use, fully disposable devices and/or components is an option to reduce the risk of virus transmission from surface contact.” The trend towards disposable HSATs has continued to develop beyond the conclusion of the PHE, given the many other clinical and operational advantages offered by disposable technology.⁵ Among other things, disposable HSAT technology reduces patient burden (travel time, expense, absence from work), especially for elderly patients with limited transportation access, expands sleep testing access to underserved patients and remote geographic areas, and provides faster results leading to more rapid treatment and consistent follow-up.

III. CPT 95800: PROPOSED UPDATES TO SUPPLY AND EQUIPMENT INPUTS

As discussed in the sections above, the current direct PE inputs are valued with inputs that describe reusable equipment (e.g., the WatchPAT 200 Unit), and do not account for the more frequently utilized cost of the WatchPAT ONE device as a single-use supply for this service. As the disposable device utilization ratio continues to increase, Itamar believes that the “typical” procedure reported with code 95800 in CY 2024 and beyond will use a disposable HSAT device, not reusable equipment. Accordingly, the direct PE resources that are “required for the typical service” will align with the use of disposable, not reusable, test equipment—consistent with CMS’ standard methodology for establishing Direct Practice Expense inputs.⁶

To reflect the resource costs associated with disposable HSAT technology, Itamar requests that CMS update the direct PE inputs for CPT code 95800 to: (1) remove the reusable equipment codes (EQ335 and EQ336) and the supply code associated with reusable equipment (SD263, single-use probes used with reusable WatchPAT unit); and (2) add supply code SD362 (the disposable WatchPAT ONE device).

a. Proposed Equipment Input Changes

The current equipment inputs for CPT 95800 are EQ335 (describing the reusable WatchPAT 200 and related accessories) and EQ336 (describing a traditional airflow test device). CMS should **remove** both codes to reflect the shift away from reusable equipment in favor of a single-use disposable supply:

⁵ AASM, Considerations for the practice of sleep medicine during COVID-19, <https://aasm.org/covid-19-resources/considerations-practice-sleep-medicine> (last visited Feb. 1, 2024).

⁶ *Id.* at 78,892.



EQUIPMENT INPUTS: PROPOSED UPDATES						
CPT	Category	Equip Code	Description	Price	Equip Cost Per Minute	Equipment Status
95800	OTHER-EQUIPMENT	EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	1,237.5	4.707	DELETE
95800	OTHER-EQUIPMENT	EQ336	Oximetry and Airflow Device	1,195	4.545	DELETE

b. Proposed Supply Input Changes

The current SD263 supply code describes single-use WatchPAT probes used with the reusable WatchPAT equipment. The new WatchPAT One supply code (SD362) is an entire, single-use HSAT testing system that effectively replaces both the reusable HSAT testing units (EQ335 and EQ336) and the single-use WatchPAT probes (SD263). To reflect this configuration, CMS should **remove** supply code SD263 and **add** the new supply code SD362 to describe the WatchPAT One system:

SUPPLY INPUTS: PROPOSED UPDATES							
CPT	Category	Supply Code	Description	Price	Quantity	Supply Cost	Supply Status
95800	Accessory-Procedure	SD263	WatchPAT pneumo-opt slp probes	73.32	1	73.32	DELETE
<u>95800</u>	<u>Accessory-Procedure</u>	<u>SD362</u>	<u>WatchPAT ONE device</u>	<u>98.20</u>	<u>1</u>	<u>98.20</u>	<u>ADD</u>
95800	Wound Care, Dressings	SG005	adhesive remover, liquid (Detachol) (0.67ml uou)	2.4	1	2.4	RETAIN
95800	Wound Care, Dressings	SG078	tape, surgical occlusive lin (Blenderm)	0.007	8	0.056	RETAIN
95800	Pharmacy, NonRx	SJ053	swab-pad, alcohol	0.04	5	0.2	RETAIN
95800	Office Supply, Grocery	SK057	paper, laser printing (each sheet)	0.02	2	0.04	RETAIN
95800	Infection Control	SM021	sanitizing cloth-wipe (patient)	0.07	2	0.14	RETAIN
95800	Infection Control	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	0.07	2	0.14	RETAIN

Establishing direct PE inputs consistent with the adjusted equipment and supply inputs described above for code 95800, while retaining current labor and malpractice inputs, would result in an accurate valuation that reflects the costs associated with disposable HSAT device services.

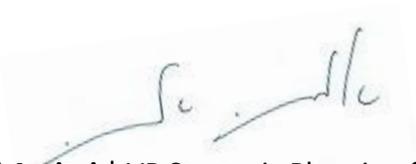


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Itamar appreciates CMS' attention to this important issues and thanks the Agency for its consideration of these comments. As described in detail above, Itamar believes that 95800 is misvalued and requests that CMS update the direct PE inputs to recognize the changing utilization patterns for code 95800 and provide adequate payment to physicians for the increased costs of utilizing the disposable technology to perform that service.

Should you have any questions about the contents of this letter, please do not hesitate to contact Etai Amitai at etai.amitai@zoll.com.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Etai Amitai".

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