Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RADs), Including Bi-Level PAP Benefit Criteria to Change for Texas Medicaid Effective March 1, 2017

Overview of Benefit Changes

- Benefit criteria for CPAP and RADs have been expanded and are based on Centers for Medicare & Medicaid Services (CMS) coverage determinations.
- The Home Health Services (Title XIX) DME/Medical Supplies Physician Order Form is no longer required for CPAP or RAD prior authorization requests. All CPAP and RAD prior authorization (Fee-For-Service) requests must be submitted using the Texas Medicaid Prior Authorization Request for CPAP or RAD (BI-level PAP) form.
- Prescribing providers must maintain the original, completed, signed and dated Texas Medicaid Prior Authorization Request for CPAP or RAD (BI-level PAP) in the client's medical record. The DME provider needs to maintain a copy of the completed, signed, and dated form in the client's record.
- Chinstrap (procedure code A7036) will be a new benefit.
- Related supplies (procedure codes A7027 through A7036) do not require prior authorization when requested within the defined limits except when used with procedure code E0472, as supplies are included in the rental of a RAD *with* backup rate when used with an invasive interface.
- Providers are encouraged to read the CPAP and RADs benefit limitations and reimbursement outlined in the "Covered Procedure Codes and Benefit Limitations" table which can be found in the article titled "Benefit Criteria to Change for Respiratory Equipment and Supplies Effective March 1, 2017"

Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RADs) including Bi-Level PAP

CPAP and RAD criteria are based on Centers for Medicare & Medicaid Services (CMS) coverage determinations.

Continuous positive airway pressure (CPAP) (procedure code E0601) and respiratory assist devices (RADS) (procedure codes E0470, E0471, E0472), which include bi-level positive airway pressure (PAP) *with* or *without* a set backup respiratory rate are a benefit when medically necessary and may be considered for rental or purchase with prior authorization (Fee-For-Service) for clients requiring:

- Treatment of obstructive sleep apnea
- Restrictive thoracic disorders
- Severe chronic obstructive pulmonary disease
- Central sleep apnea
- Complex sleep apnea

- Hypoventilation syndrome.

Only when medically necessary are RADs *with* a set backup respiratory rate available for rental.

Other conditions may be considered based on medical necessity.

Humidification devices (heated and non-heated) may be a benefit with prior authorization (Fee-For-Service) when medically necessary for rental or purchase for use with CPAP devices and RADs. CPAP devices deliver a single, fixed pressure to the client during the night while sleeping. Some sleep breathing disorders do not benefit from CPAP and require treatment with RADs that are able to recognize the client's breathing patterns and adjust pressure during the respiratory cycle during sleep.

Headgear, chinstraps, face masks, nasal pillows, cushions, nasal interfaces, tubing, and filters for CPAP and RADs within the maximum allowed limits do not require prior authorization.

Exception: RAD *with* backup rate used with an invasive interface (procedure code E0472) does require prior authorization (Fee-For-Service) and supplies will not be authorized separately as they are included in the rental. Providers may refer to the table titled “Respiratory Assist Device (RAD) & CPAP Procedure Code Billing Relationships,” which can be found in the article titled “Benefit Criteria to Change for Respiratory Equipment and Supplies Effective March 1, 2017,” for a complete list of related supplies that will deny as part of a procedure code E0472 rental.

With a fee-for-service history of a client-owned CPAP and RAD accessories (procedure codes A7027 through A7036), do not require prior authorization within the maximum allowed limits.

In the case of a client-owned RAD *with* backup rate that is used with an invasive interface (procedure code E0472) that was purchased as a result of a rental or purchased through another payer source, proof of ownership of the device is required for consideration of reimbursement of associated supplies and accessories. A statement from the treating physician providing the make and model of the client-owned device, submitted with the claims appeal, will meet this requirement when a claims history is not available.

A CPAP device or a RAD *without* a set backup rate may be considered for an *initial* three-month rental period with prior authorization (Fee-For-Service). Following the *initial* three-month rental period, if the CPAP or RAD *without* a set backup rate is effective the device may be considered for purchase. Both devices may also be considered for continued rental with *renewal* at 3 month intervals up to 12 months.

A CPAP device and a RAD *without* a set backup rate will be considered purchased after 12 months of rental through the same provider and a request for purchase or further rental will not be considered.

A RAD *with* a set backup respiratory rate requires prior authorization (Fee-For-Service) and may be considered only for rental.

Humidification devices (heated or non-heated) for use with a CPAP or RAD device may be a benefit with prior authorization (Fee-For-Service) when medically necessary. Documentation submitted must support why humidification is medically necessary for use with positive pressure ventilation.

Prior Authorization (Fee-For-Service)

Prior authorization may be considered for *initial* and *renewal* requests for CPAP and RADs, with submission of all of the following:

- A Texas Medicaid Prior Authorization Request for CPAP or RAD (Bi-level PAP) form (new with each request) completed, signed, and dated by the treating physician
    - Sections A and B must be completed for *initial* requests
    - Sections A and C must be completed for *renewal* requests
- Additional documentation (e.g., titration sleep studies) as necessary to support the medical necessity of the service required as outlined below for the *initial* and *renewal* requests

Initial Request for a Continuous Positive Airway Pressure (CPAP) System

The American Academy of Sleep Medicine (AASM) Guidelines state that it is clinically appropriate to treat clients who are 18 through 20 years of age using adult criteria.

A CPAP device (procedure code E0601) may be considered for an *initial* three-month rental period based on documentation supporting the medical necessity and appropriateness of the device when all of the following conditions are met:

- Documentation that the client has had a sleep study, lasting a minimum of two hours, and meeting at least one of the following criteria:
    - For clients who are 17 years of age and younger, polysomnography results documenting an apnea-hypopnea index (AHI) greater than one event per hour may be used to establish medical necessity.
    - For clients who are 18 years of age and older, polysomnography results documenting an AHI or a respiratory disturbance index (RDI) greater than or equal to 15 events per hour
    - For clients who are 18 years of age and older, an AHI or RDI greater than five events per hour with documentation of at least one of the following:
        - Excessive daytime sleepiness assessed by either the Epworth Sleepiness Scale (ESS) with a result greater than 10 or the Multiple Sleep Latency Test (MSLT) with a result less than 6
        - Symptoms of impaired cognition, mood disorders, or insomnia
        - Hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg)
        - Ischemic heart disease or previous myocardial infarction
        - History of stroke
        - Greater than 20 episodes of oxygen desaturation to less than 85 percent during a full night sleep study
        - Any one episode of oxygen desaturation of less than 70 percent
        - Pulmonary hypertension
- CPAP may be medically necessary for the treatment of obstructive sleep apnea (OSA) in clients who are 18 years of age and younger when one of the following criteria are documented:

    - Adenoidectomy or tonsillectomy is contraindicated
    - Adenoidectomy or tonsillectomy is delayed
    - Adenoidectomy or tonsillectomy has been unsuccessful in relieving symptoms of OSA
- Documentation must be maintained by the provider in the client's medical record that the client or responsible caregiver has received instruction from the DME provider on the proper use and care of the device and supplies.

Renewal Request for a CPAP System

Prior authorization (Fee-For-Service) for purchase or an additional three months CPAP rental after the *initial* three-month rental period will be considered with all of the following documentation completed, signed, and dated by the client's treating physician:

- A new Texas Medicaid Prior Authorization Request for CPAP or RAD (Bi-level PAP) form.
- Documentation of medical necessity supporting:
    - The client's continuous use of the equipment for a minimum of 4 hours per 24-hour period
    - The client's symptoms as documented by the treating physician are improved with use of the CPAP
- Continued rental of CPAP may be considered for up to 12 months of continuous *renewal* at 3-month intervals.
- A CPAP device will be considered purchased after 12 months of continuous rental through the same provider.

Initial Request for Respiratory Assist Devices (RADs), including BiPAP– *with* and *without* a Set Backup Respiratory Rate

A RAD *with* or *without* a set backup rate may be considered for prior authorization (Fee-For-Service) when the client has one of the following medical conditions as documented by a sleep study and meets criteria for medical necessity for the specific medical condition:

- Obstructive sleep apnea (OSA)
- Restrictive thoracic disorders (e.g., neuromuscular diseases or severe thoracic cage abnormalities)
- Severe Chronic Obstructive Pulmonary Disease (COPD)
- Central sleep apnea (CSA), complex sleep apnea (CompSA)
- Hypoventilation syndrome

Initial Request for RAD for the Treatment of Obstructive Sleep Apnea (OSA)

A RAD *without* backup may be considered for an *initial* three-month trial period, with prior authorization (Fee-For-Service), for the treatment of OSA with prior authorization and submission of all of the following:

- All the required documentation delineated on the Texas Medicaid Prior Authorization Request for CPAP or RAD (Bi-level PAP) form
- The client meets the criteria for the *initial* CPAP rental
- The documentation supports that CPAP has been tried and one of the following is documented:
    - The client's treating physician verifies that a therapeutic trial of CPAP was conducted in the home or a facility setting and failed to be effective in treating the client's OSA.
    - A CPAP device was found to be ineffective during the initial facility based or sleep laboratory titration trial testing.

If a CPAP device is tried and found ineffective during the initial facility-based titration or home trial, substitution of a RAD does not require a new face-to-face clinical evaluation or a new sleep test.

Initial **Request for RAD for the Treatment of Restrictive Thoracic Medical Conditions**

A RAD *without* a set backup rate requires prior authorization (Fee-For-Service) and may be considered for the treatment of thoracic medical conditions when all of the following are met:

- The client is diagnosed with a neuromuscular disorder (e.g., Duchenne muscular dystrophy, ALS, spinal cord injuries) or the client has a diagnosis of a severe thoracic cage abnormality (e.g., severe chest wall deformities) negatively impacting the client's respiratory effort.
- Significant respiratory insufficiency is documented by one of the following:
    - An arterial blood gas (ABG) $PaCO_2$ greater than or equal to 45 mm Hg, obtained while awake and breathing the client's routinely prescribed FIO_2
    - Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours), obtained while client is breathing his or her routinely prescribed FiO_2

NOTE*: FIO_2 (fraction of inspired oxygen concentration) is the concentration of oxygen prescribed for routine use by the client. For example, if the client does not normally use supplemental oxygen, their prescribed oxygen is room air (FiO_2 of 21 percent).*

For clients who have been diagnosed with a neuromuscular disorder only, documentation must support one of the following:

- Maximal inspiratory pressure less than 60 cm H_20
- Forced vital capacity less than 50 percent of predicted

A RAD *with* a set backup rate requires prior authorization (Fee-For-Service) and may be considered for the treatment of thoracic medical conditions when all of the following are met:

- The client meets the criteria for use of the RAD *without* a backup rate for the treatment of a thoracic medical condition.

- The ordering physician certifies to all of the following:
    - Client has tried a RAD *without* a backup rate for at least 60 days.
    - The client was compliant in the use of the device (using on average 4 or more hours in a 24-hour day).
    - The desired therapeutic respiratory response was not achieved with the RAD *with*out a set backup rate.

Initial Request for RAD for the Treatment of Severe Chronic Obstructive Pulmonary Disease (COPD)

A RAD *without* a backup rate may be considered for the treatment of severe COPD, with prior authorization (Fee-For-Service), when all of the following criteria are met:

- An arterial blood gas $PaCO_2$ less than 52 mm Hg, obtained while awake and when the client is either using 2 LPM of oxygen or the client's prescribed FIO_2 (the blood gas should be drawn while the client is using whichever concentration of oxygen is the higher of the two).
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours), obtained while breathing oxygen at 2 LPM or the client's prescribed FIO_2 (whichever is higher).
- Prior to initiating therapy, documentation of sleep apnea and that treatment with CPAP has been considered with an explanation of why it was ruled out.

To rule out the use of a CPAP, formal sleep testing is not required if there is sufficient information in the medical record submitted with the request to demonstrate that the client does not suffer from some form of sleep apnea (obstructive sleep apnea (OSA), CSA, or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation.

A RAD *with* a backup feature will be considered with prior authorization (Fee-For-Service) for severe COPD when the all of the following criteria are met:

- The client meets the criteria for use of the RAD *without* a backup rate for COPD
- The ordering physician certifies to all of the following:
    - Client has tried a RAD *without* a backup rate for at least 60 days
    - The client was compliant in the use of the device (using on average 4 or more hours in a 24-hour day)
    - The desired therapeutic respiratory response was not achieved with the RAD *without* a set backup rate

Initial Request for RAD for the Treatment of Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)

CSA or CompSA is characterized by the development of central apneas or central hypopneas during pressure titrations performed in a sleep lab titration study for CPAP or RAD *without* a backup rate.

A RAD *without* a backup rate will be considered with prior authorization (Fee-For-Service) for the treatment of CSA or CompSA when a facility based polysomnogram is performed and supports all of the following:

- The client has a diagnosis of CSA or CompSA.
- The sleep study documents one of the following:
    - The sum total of central hypopneas plus central apneas is greater than 50 percent of the total apneas and hypopneas rate.
    - A central hypopnea/apnea rate index greater than five events per hour; and significant improvement of the sleep-associated hypoventilation while breathing the clients prescribed FiO_2.
    - Documentation ruling out CPAP as effective therapy if either OSA or CSA is a component of the initially observed sleep associated hypoventilation.

A RAD *with* a backup rate will be considered with prior authorization (Fee-For-Service) for the treatment of CSA or CompSA when all of the following are met:

- The client meets the criteria for use of the RAD *without* a backup rate for the treatment of CSA or CompSA.
- The ordering physician certifies to all of the following:
    - The client as tried a RAD *without* a backup rate for at least 60 days.
    - The client was compliant in the use of the device (using on average 4 or more hours in a 24-hour day).
    - The desired therapeutic respiratory response was not achieved with the RAD *without* a set backup rate.

Initial Request for RAD for the Treatment of Hypoventilation Syndrome

A RAD *without* a backup rate may be considered for treatment of hypoventilation syndrome with prior authorization (Fee-For-Service) when all of the following criteria are met:

- An initial arterial blood gas $PaCO_2$, obtained while awake with the client breathing their prescribed FIO_2, greater than or equal to 45 mm Hg
- Spirometry shows a forced expired volume in 1 sec (FEV1) or the forced vital capacity (FVC) greater than or equal to 70 percent
- A facility-based polysomnogram demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours) not caused by obstructive upper airway events.

A RAD *with* a set backup respiratory rate may be considered with prior authorization (Fee-For-Service) for the treatment of hypoventilation syndrome when one of the following are met:

- The client has hypoventilation syndrome as determined by a facility-based polysomnogram that demonstrates the desired respiratory therapeutic effects were not achieved with a RAD *without* a backup rate.

- The client meets the criteria for RAD *without* a backup rate for hypoventilation syndrome, and the physician documents the desired respiratory therapeutic effects were not achieved with the RAD *without* a backup rate.

Renewal **Request for RAD with or without a Backup Rate**

Prior Authorization (Fee-For-Service) is required for *renewal* of a RAD *with* or *without* a backup rate.

Prior authorization (Fee-For-Service) for purchase of RAD *without* a set backup rate or continued rental of a RAD *with* or *without* a backup rate, after completion of the *initial* three-month rental period, may be considered with all of the following documentation completed, signed, and dated by the client's treating physician:

- A new Texas Medicaid Prior Authorization Request for CPAP or RAD (Bi-level PAP) form
- Attestation from the treating physician that states the client is continuing to use the equipment at a minimum of 4 hours in a 24 hour period
- Client symptoms are improved as documented by the client's treating physician.

When recertifying a RAD *with* or *without* a set backup rate for significant respiratory insufficiency, documentation of a capillary blood gas (CBG) demonstrating a $PaCO_2$ greater than or equal to 45 mm Hg, obtained while awake and breathing the client's routinely prescribed FiO_2 may be submitted in lieu of an ABG.

Providers may refer to the “Covered Procedure Codes and Benefit Limitations” table which can be found in the article titled “Benefit Criteria to Change for Respiratory Equipment and Supplies Effective March 1, 2017,” for additional details for each procedure code. These details include maximum quantity limitations, rental versus purchase options and prior authorization requirements.