MEDICAL COVERAGE POLICY	
SERVICE: Incontinence Alarms	
Policy Number:	**048**
Effective Date:	**12/01/2020**
Last Review:	**10/24/2020**
Next Review Date:	**10/24/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Incontinence: Bedwetting Alarms for Nocturnal Enuresis

PRIOR AUTHORIZATION: Not required.

POLICY: Modalities of treatment for nocturnal enuresis include ruling out an underlying physiological condition, behavioral training, pharmacotherapy, and alarms. Review of the scientific, peer-reviewed literature suggests that conditioning through the use of bedwetting (i.e., enuresis) alarms provides the best long-term outcome for management of nocturnal enuresis. The literature indicates that the alarm method has the best sustained, long-term efficacy of any behavioral or pharmacological treatment.

Coverage for bedwetting alarms is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, bedwetting alarms may be specifically excluded under some benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative. In addition, education, training, and behavioral training are specifically excluded under many benefit plans. Bedwetting alarms are considered behavioral training devices and are therefore generally not covered. Please refer to the applicable benefit plan documents to determine benefit availability and the terms and conditions of coverage.

If coverage for bedwetting alarms is available, the following conditions of coverage apply:

SWHP/FirstCare covers bedwetting alarms under the Durable Medical Equipment (DME) benefit as medically necessary when the following criteria are met:

- The member is at least 7 years old; **AND**
- The member has experienced bedwetting a minimum of 3 nights a week in the previous month, or at least 1 episode weekly of bedwetting for over 1 year; **AND**
- The member has no daytime wetting; **AND**
- The member has been thoroughly evaluated and physical or organic causes for nocturnal enuresis (e.g., renal disease, neurological disease, infection, etc.) have been excluded.

OVERVIEW: Bedwetting alarms are commonly used to treat nighttime bedwetting (i.e., nocturnal enuresis) in children and adolescents. Enuresis is defined as the repeated, involuntary voiding into

the bed or clothing after a person has reached an age at which continence is expected. When it occurs at night, it is termed nocturnal enuresis; daytime incontinence is termed diurnal enuresis (Moser, 2007). Nocturnal enuresis is a common problem, affecting an estimated five to seven million children in the United States. It occurs three times more often in boys than in girls. For a diagnosis of nocturnal enuresis to be established, a child of five to six years should have two or more bedwetting episodes per month, and a child older than six should have one or more bedwetting episodes per month (Thiedke, 2003). Enuresis is defined as primary when the child has never established a sixmonth period of urinary continence or secondary if the child becomes incontinent after a six-month period of continence (Blum, 2004). Diagnosis should include ruling out other causes of incontinence, such as infection, diabetes, and urological and neurological disorders. A carefully obtained history, physical examination and urinalysis usually constitute a sufficient evaluation for most children to establish primary nocturnal enuresis (Yeung, 2007). At five years of age, 15–25% of children wet the bed. With each year of maturity, the percentage of children who wet the bed declines by 15%. Current theories suggest that there may be many causes of nocturnal enuresis,including genetic predisposition, bladder capacity, insufficient arginine vasopressin, constipation, psychological factors and sleep disorders (Thiedke, 2003). Simple behavioral and physical interventions are commonly used to treat nocturnal enuresis, and they appear to have a more significant effect than having no intervention (Glazener, et al., 2005). The following interventions are widely used as initial, first-line treatments for families (Moser, 2007):

- teaching families to reward dry nights
- avoiding punishment for wet nights
- lifting or waking the child to void after going to sleep
- responsibility training
- limiting fluids prior to bedtime

Education of the child and family is crucial in the management of nocturnal enuresis, and the timing of treatment needs to be individualized. It is important that the child be motivated to take an active role in the process (Thiedke, 2003). There are various types of bedwetting or enuresis alarms that are used to treat nocturnal enuresis. The alarm may be a bell or buzzer; a visual signal, such as a light; or a device that vibrates. The alarm is activated and awakens the child when the sensor becomes moist during the child's voiding. Some of the systems involve a sensor placed inside a pad on the bed which activates the alarm. Newer systems generally have a sensor that attaches to clothing or undergarments. The child is awakened and can then get out of bed to finish voiding in the bathroom. For resolution of nocturnal enuresis, the bedwetting alarm may need to be used for several months. Alarms that provide a shock can cause burns and are therefore not considered safe (Thiedke, 2003; Glazener, et al., 2005).

Examples of these devices include, but are not limited to:

- Malem Bedwetting Alarm (Malem Medical, Nottinghamshire, United Kingdom)
- WetiX, Wetless Nights (Z-Pack, Inc., Woodland Hills, CA.)
- Nytone Enuretic Alarm (Salt Lake City, UT)
- Potty Pager (Boulder, CO)
- DRI Sleeper® bedwetting alarms (AnzAcare Ltd, New Zealand)

According to the FDA, enuresis alarms are considered Class II medical devices and are subject to approval by the FDA. The FDA identifies the device as: "An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm

when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms." The FDA has determined that these devices are exempt from the premarket 510(k) notification procedure, and the manufacturer is not required to supply to the FDA evidence of the effectiveness of the enuresis alarm prior to marketing the device (FDA, 2005).

Multiple, systematic Cochrane systematic reviews of the literature have been conducted to determine the effectiveness of various interventions in the treatment of children with nocturnal enuresis. The studies evaluated the use of alarm systems, simple behavioral interventions, complex behavioral interventions and various medications (i.e., either alone or in combination with alarms), for children with nocturnal enuresis.

Fifty-six randomized or quasi-randomized studies of 3,257 children with nocturnal enuresis were included in a Cochrane review for the use of alarm interventions (Glazener, et al., 2005). Comparison interventions included no active treatment (control), use of simple and complex behavioral methods, use of desmopressin or tricyclic medications, and miscellaneous other medications or methods. The outcomes considered were:

- change in the number of wet nights per week during treatment
- number of participants failing to attain 14 consecutive dry nights
- mean number of wet nights after treatment concluded
- number failing to attain 14 consecutive dry nights or relapsing
- adverse events

The evidence suggests that the use of alarm systems reduces the number of wet nights by the end of the course of treatment, and that the effects are generally sustained better than other treatment options for nocturnal enuresis. Compared to no treatment, approximately two-thirds of the children become dry with the use of an alarm system. There is insufficient evidence to suggest that one type of alarm is better than another or to support combining an alarm with drug intervention. Although medication may have a more immediate effect than an alarm, most children relapse after active drug treatment is stopped. Additionally, since there are associated risks of side effects with medication use, alarms are preferable to pharmacological options. Overlearning (i.e., giving a child extra fluids at bedtime after successfully becoming dry by use of an alarm) and avoiding penalties may help to further reduce the relapse rate.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
ICD10 codes:	N39.44 Nocturnal enuresis
HCPCS codes:	S8270 Enuresis alarm, using auditory buzzer and/or vibration device

CMS: CMS NCD 30.1.1 was found for biofeedback therapy for the treatment of urinary incontinence, but there is no mention of pediatric patients. Note that home use of biofeedback is not covered.

POLICY HISTORY:

Status	Date	Action

New	12/7/2010	New policy
Reviewed	12/6/2011	Reviewed.
Reviewed	10/25/2012	No changes
Reviewed	10/3/2013	Coverage criteria changed. ICD10 added.
Reviewed	07/24/2014	No changes
Reviewed	08/11/2015	No changes
Reviewed	09/08/2016	No material changes
Reviewed	08/29/2017	No changes
Reviewed	06/26/2018	Minor revisions
Reviewed	09/26/2019	No changes
Reviewed	10/24/3030	Added criteria for more urgent situation

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP/FirstCare so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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