



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Bedwetting Alarm for Nocturnal Enuresis

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Coverage Policy Number 0044

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Hyperlink to Related Coverage Policies

Biofeedback

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

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 are 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.

CIGNA covers bedwetting alarms under the Durable Medical Equipment (DME) benefit as medically necessary when BOTH of the following criteria are met:

- The child has been thoroughly evaluated, and other causes of nighttime bedwetting, such as infection, have been excluded.
- EITHER of the following apply:

- The child is between age five and six years and has two or more bedwetting episodes per month.
 - The child is age six years or older and has one or more bedwetting episodes per month.
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General Background

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 six-month 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)

U.S. Food and Drug Administration (FDA)

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).

Literature Review

Cutting et al. (2007) reported on the outcomes and follow-up of children with monosymptomatic nocturnal enuresis (MNE) utilizing body-worn bedwetting alarms. MNE was defined as "The involuntary voiding of urine during sleep in children over the age of 5 years in the absence of congenital or acquired abnormalities of the urogenital system, where there has been no prolonged dryness for 6 months or more and no bladder or voiding problems associated with their wetting." The prospective study included 505 children with MNE with outcomes assessed at six and 24 months. At a median of 10 weeks, 79% had achieved initial dryness. Of those achieving initial dryness, 73% remained dry at six months, and 64% remained dry at 24 months. A follow-up rate of 99.2% was achieved. Nineteen percent of the children required greater than 16 weeks of treatment, with 56% of them achieving dryness. The authors concluded that MNE can be successfully managed through the use of body-worn alarms and that initial and long-term complete dryness could be achieved without the use of pharmacologic intervention.

Naitoh et al. (2005) compared alarm monotherapy to alarm therapy combined with desmopressin and alarm therapy combined with imipramine. A total of 105 patients were included. Of them, 37 were treated with the alarm monotherapy, 35 were treated with the combined alarm/desmopressin therapy, and 33 were treated with the combined alarm/imipramine therapy. Therapeutic effect was evaluated at three and six months. Relapse rates and predictive factors were also studied. At three months, there was no difference in frequency of wet nights among the three groups, although there was a significant decrease in the frequencies in all three groups with improvement rates of 57% for the monotherapy group, 60% for the desmopressin group, and 67% for the imipramine group. At six months, the improvement rate for the desmopressin and imipramine group was higher at 80% and 79%, respectively, compared to 59% in the monotherapy group. No patients relapsed in the monotherapy group, whereas three patients in each of the other groups did relapse. No predictive factors for the therapeutic effects in the three modalities were found. The authors concluded that at three months, desmopressin and imipramine combined with an alarm was no more effective than alarm monotherapy and that other therapies should be considered if, after three months, alarm monotherapy has not proved effective.

Fai-NGO et al. (2005) conducted a nine-center, randomized controlled trial to compare the "efficacy of enuresis alarms, oral desmopressin, and combined treatment in Chinese children with monosymptomatic primary nocturnal enuresis." Children were randomly assigned to three groups. Group one received alarms (n=35); group two received oral desmopressin (n=38); and group three received combination therapy (n=32). Children were included who were 7–15 years of age and had a wetting frequency of three or more nights a week for two consistent weeks prior to the study. Exclusion criteria were followed. Outcomes were measured by the number of wet nights per week over a four-week period of time. Patients were followed for 12 weeks after the cessation of treatment. Desmopressin produced an immediate effect, but relapses occurred. Alarms took longer to show improvement, but the results were persistent.

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.

Glazener et al. (2004a) reviewed 13 small trials of simple behavioral interventions commonly used in children who experience nocturnal enuresis. The methods reviewed were waking, retention control training, fluid restriction, reward systems such as star charts, and avoidance of punishment. The conclusions indicate that simple behavioral methods may be better than doing nothing. Since they do not appear to have side effects or safety concerns, they could be considered as first-line treatment. There was insufficient evidence to demonstrate that these interventions were more effective than other means of treatment. The authors concluded that the primary benefit of these methods may be the promotion of a positive family culture in response to dry nights rather than a negative environment of punishment.

Glazener et al. (2004b) conducted a Cochrane review of complex behavioral and educational interventions for nocturnal enuresis. The review included 18 trials that involved 1,174 children. Complex interventions included dry bed training (DBT), in which the individual was awakened every hour to toilet. If an accident occurred, reprimands, cleanliness training, and frequent toileting practices were employed. Full-spectrum home training (FSHT), which combined the use of an alarm with cleanliness training, retention control training and overlearning, was also studied. The results showed that, although DBT and FSHT were better than no treatment, there was insufficient evidence to support their use without an alarm. Use of an alarm on its own was better than DBT alone.

Glazener et al. (2003b) also reviewed 54 trials utilizing tricyclic drugs to treat nocturnal enuresis. The medications were found to reduce nocturnal enuresis; however, the use of alarms was found to be more effective. Most children experienced a relapse after the medication was discontinued. Tricyclics also have significant adverse effects.

Glazener et al. (2002) reported on a Cochrane review of desmopressin use in children with nocturnal enuresis. The review included 47 randomized controlled trials involving 3448 children. Desmopressin is an analogue of the human pituitary hormone arginine vasopressin. Its antidiuretic effect results from increased reabsorption of water from the kidney, decreasing urine volume to the bladder. Use of desmopressin was found to be beneficial compared to placebo treatments and resulted in fewer wet nights; however, after treatment was discontinued, the improvement was not sustained. In four small trials, there was no significant differences between desmopressin when combined with alarm treatment when compared to alarm used alone; however, the chance of failure or relapse after treatment stopped was lower after an alarm in two small trials.

Professional Societies/Organizations

The American Academy of Child and Adolescent Psychiatry (AACAP) published practice parameter for the assessment and treatment of children and adolescents with enuresis, based on evaluation of the scientific literature and clinical consensus. The practice parameters state that conditioning with an alarm along with behavioral therapies is a highly effective first-line treatment for nocturnal enuresis in cooperative, motivated families. Medication use may be considered if conditioning treatment fails or is not feasible (Fritz, et al., 2004).

The Pediatric Society of New Zealand published best practice guidelines on nocturnal enuresis. The guidelines report that “enuresis alarm programs are the treatment of choice in motivated children over seven years.” The society reports that the initial success of the alarms alone is 65–80%. The alarms are more effective than behavioral motivation and pharmacotherapy (Pediatric Society of New Zealand, 2005).

The European Association of Urology and European Society for Pediatric Urology published evidenced-based guidelines on pediatric urology (Tekgul, et al., 2008). In the section on monosymptomatic enuresis, they include the recommendation that, alarm treatment is the best form of treatment for arousal disorder, or a lack of arousal from sleep to void. They note that, "Initial success rates of 80% with low relapse rates are realistic, especially when night-time diuresis is not too high and bladder capacity is not too low."

Summary

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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
S8270	Enuresis alarm, using auditory buzzer and/or vibration device

ICD-9-CM Diagnosis Codes	Description
788.36	Nocturnal enuresis

*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	4/15/2007	0044	Bedwetting Alarm for Nocturnal Enuresis

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