

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Nocturnal Polyuria Clinical Edit
<b>First Implementation Date:</b>	August 22, 2019
<b>Proposed Date:</b>	March 19, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of agents for Nocturnal Polyuria

**Why Issue Selected:** Nocturia is the need to wake up to urinate during the night; Nocturnal polyuria (NP) is the leading cause of nocturia, present in up to 88% of nocturia patients. With NP, the kidneys overproduce urine at night causing nighttime awakenings to empty the bladder (at least 2 instances per night). NP occurs when the volume of nighttime urine production by the kidney exceeds > 1/5 of daily urine total in patients less than 65 years old or > 1/3 of daily urine in patients greater than 65 years old. NP is also present in a majority of patients with overactive bladder or benign prostatic hyperplasia (BPH). Noctiva™ and Nocdurna® are both FDA approved for the treatment of NP in adults who awaken at least 2 times per night to void.

### Program-Specific Information:

Date Range FFS 1-1-2019 to 12-31-2019			
Drug	Claims	Spend	Cost per month (WAC)
Nocdurna® 27.7 mcg tab SL	0	-	\$420.00 per 30 tablets
Nocdurna® 55.3 mcg tab SL	0	-	\$420.00 per 30 tablets
Noctiva™ 0.83 mcg/0.1 ml spray	0	-	\$425.00 per 30 sprays
Noctiva™ 1.66 mcg/0.1 ml spray	3	\$1,318.10	\$425.00 per 30 sprays

- Type of Criteria:**
- Increased risk of ADE
  - Appropriate Indications
  - Preferred Drug List
  - Clinical Edit
- Data Sources:**
- Only Administrative Databases
  - Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Nocturnal Polyuria Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

- Participant aged 18 years or older **AND**

- Documented diagnosis of nocturnal polyuria in the past 2 years **AND**
- For the first claim of a nocturnal polyuria agent: documented therapeutic trial of generic desmopressin (trial defined as 45/60 days)

## Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documented diagnosis of polydipsia in the past 12 months
- Documented or inferred diagnosis of heart failure in the past 2 years
- Claim for any loop diuretic in the past 45 days
- Claim for any oral or inhaled corticosteroid in the past 45 days

## Required Documentation

Laboratory Results:   
 MedWatch Form:

Progress Notes:   
 Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
 Rule Type: CE

## Default Approval Period

1 year

## References

- NOCTIVA™ (desmopressin acetate) nasal spray, [package insert]. Milford, PA: Serenity Pharmaceuticals, LLC; March 2017.
- NOCDURNA® (desmopressin acetate) sublingual tablets [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; June 2018.
- Ferring Pharmaceuticals Inc. Nocturnal Polyuria – Treat Nocturia due to Nocturnal Polyuria in Adults. <https://nocturnalpolyuria.com/>. Accessed 2/13/2020.
- IPD Analytics. Urology: Overactive Bladder and Frequent Nightly Urination. Accessed 2/13/2020.