SmartPA Criteria Proposal

Drug/Drug Class:	Nocturnal Polyuria Clinical Edit
First Implementation Date:	August 22, 2019
Proposed Date:	March 19, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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**

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- 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 crieria 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:		Progress Notes:	
MedWatch Form:		Other:	X

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.

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