Vaprisol (conivaptan)
Policy Number: C15199A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/1/2018	8/1/2018	8/1/2019
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J3490	RxPA	Q3 2018

PRODUCTS AFFECTED:
Intravenous injection solution; conivaptan hydrochloride 20 mg/100 ml premixed in 5% dextrose in flexible plastic containers.

DRUG CLASS:
Electrolytic and Renal agents

ROUTE OF ADMINISTRATION:
For intravenous use only. Infusion site reactions are common. Administer VAPRISOL through large veins and change of the infusion site every 24 hours to minimize the risk of vascular irritation.

PLACE OF SERVICE:
Buy and Bill

AVAILABLE DOSAGE FORMS:
Intravenous injection solution; conivaptan hydrochloride 20 mg/100 ml premixed in 5% dextrose in flexible plastic containers.

FDA-APPROVED USES:
VAPRISOL is a vasopressin receptor antagonist indicated to raise serum sodium in hospitalized patients with euvolemic and hypervolemic hyponatremia.

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Hyponatremia
REQUIRED MEDICAL INFORMATION:
A. HYPONATREMIA:
1. Patient must be hospitalized (Provider must submit hospital chart notes)
   AND
2. CMP (moderate to severe hyponatremia, serum sodium < 130 mEq/L)
   AND
3. Labs/documentation showing that fluid restriction and sodium chloride administration were not sufficient to correct hyponatremia.
   AND
4. Documenation of the following: Volume status, Renal and liver function tests, Child-Pugh Score, Vital signs

DURATION OF APPROVAL:
Initial authorization: 4 days, Continuation of Therapy: up to 4 days

QUANTITY:
Initiate with a loading dose of 20 mg administered IV over 30 minutes, follow the loading dose with 20 mg administered in a continuous IV infusion over 24 hours. After the initial day of treatment, administer for an additional 1 to 3 days in a continuous IV infusion 20 mg/day. If serum sodium is not rising at the desired rate, may be titrated upward to a maximum dose of 40 mg daily. Total duration of infusion (after the loading dose) should not exceed four days.

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a nephrologist

AGE RESTRICTIONS:
18 years of age and over

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. HYPONATREMIA;
1. Documenation of Serum Sodium and volume status and Vital signs
AND
2. Patient must be hospitalized (confirm with hospital progress notes)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vaprisol are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. VAPRISOL is contraindicated in patients with hypovolemic hyponatremia. The coadministration of VAPRISOL with potent CYP3A inhibitors, such as ketoconazole, itraconazole, clarithromycin, ritonavir, and indinavir, is contraindicated. Vaprisol is contraindicated in anuric patients (no benefit can be expected). For patients who develop hypovolemia or hypotension while receiving VAPRISOL, VAPRISOL should be discontinued, and volume status and vital signs should be frequently monitored. Once the patient is again euvolemic and is no longer hypotensive, VAPRISOL may be resumed at a reduced dose if the patient remains hyponatremic. VAPRISOL has not been shown to be effective for the treatment of the signs and symptoms of heart failure and is not approved for this indication.

OTHER SPECIAL CONSIDERATIONS:
The amount of safety data on the use of VAPRISOL in patients with hypervolemic hyponatremia associated with heart failure is limited. VAPRISOL should be used to raise serum sodium in such patients only after consideration of other treatment options. It has not been established that raising serum sodium with VAPRISOL provides a symptomatic benefit to patients. The effectiveness of VAPRISOL for the treatment of congestive heart failure has not been established. In 10 Phase 2/pilot heart failure studies, VAPRISOL did not show statistically significant improvement for heart failure outcomes. Overly rapid correction of serum sodium: Monitor serum sodium and neurologic status as serious neurologic sequelae can result from over rapid correction of serum sodium In patients with moderate (Child-Pugh Class B) and severe (Child-Pugh Class C) hepatic impairment, initiate VAPRISOL with a loading dose of 10 mg over 30 minutes followed by 10 mg per day as a continuous infusion for 2 to 4 days. If serum sodium is not rising at the desired rate, VAPRISOL may be titrated upward to 20 mg per day. Because of the high incidence of infusion site phlebitis (which can reduce vascular access sites) and unlikely benefit, use in patients with severe renal impairment (CLcr < 30 ml/min) is not recommended.

BACKGROUND: None

APPENDIX: None

REFRENCES:

Vaprisol® [Package Insert] Cumberland Pharmaceuticals Inc. Nashville, TN 2016