Blue Cross Blue Shield Blue Care Network of Michigan

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RETIRED

Effective Date: 04/08/2021

Giapreza™ (angiotension II)

FDA approval: December 21, 2017
HCPCS: J3490
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Second or third line therapy to increase blood pressure in adults with septic shock or other distributive shock:
      i. Despite intravenous volume resuscitation with at least 25 mL/kg over previous 24 hours AND
      ii. Administration of high-dose vasopressors (ie. norepinephrine, dopamine, vasopressin)

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing.
   b. Renewal Criteria: None

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication/Diagnosis**
   a. Giapreza is a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock

**Please refer to most recent prescribing information.*
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209360s000lbl.pdf

B. **Background Information**

a. Vasodilatory shock accounts for approximately two-thirds of all shock patients. About 6 – 7% of these cases are vasopressor resistant requiring higher doses, indicating a poor prognosis with a mortality rate of 48 – 94%. In these cases, Giapreza (angiotensin II), the first and only synthetic human angiotensin II, increases blood pressure rapidly by direct vasoconstriction, increases in sympathetic discharge, and increases in adrenal medullary catecholamine release. Giapreza also causes increased renal sodium reabsorption, and increased renal sympathetic tone.

b. Angiotensin II is a component of the renin-angiotensin-aldosterone system. As part of its mechanism of action, Angiotensin II constricts resistance vessels, thus increasing systemic vascular resistance and arterial pressure. It stimulates the release of aldosterone and vasopressin, which both increase fluid retention by the kidneys. Angiotensin II also facilitates norepinephrine release from sympathetic nerve endings and inhibits norepinephrine re-uptake leading to increased sympathetic adrenergic function.

c. The results of the ATHOS-3 multicenter, randomized, double-blind, placebo controlled phase III clinical trial demonstrated that Giapreza may be useful in catecholamine-resistant vasodilatory shock.

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. **Dosing and administration**

a. Dosing:

i. 20 - 40 ng/kg/min

**Please refer to most recent prescribing information.*

F. **How supplied**

a. 2.5 mg/mL single-dose vial

b. 5 mg/2 mL single-dose vial

References:

1. Khanna A, English SW, Wang XS, Ham K, et al. Angiotensin II for the Treatment of Vasodilatory Shock. N Engl J Med 2017;377:419-30.
2. Ghati N. The Angiotensin II for the treatment of high-output Shock-3 Trial (Athos-3). J Pract Cardiovasc Sci 2017;3:103-5.
3. Klabunde, RE. Cardiovascular Physiology Concepts. 2nd Ed Lippincott Williams & Wilkins, 2012.
4. Giapreza [package insert]. San Diego, CA: La Jolla Pharaceutical Company; December 2017.
5. La Jolla™ Pharmaceutical Corporate Presentation, Giapreza™ (angiotensin II) Update. December 2017.

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<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date: 04/08/2021</td><td>Retiring policy as drug is not managed with prior authorization</td></tr>
<tr><td>1.2</td><td>Effective Date: 4/16/2020</td><td>Annual Review</td></tr>
<tr><td>1.1</td><td>Effective Date: 05/09/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 05/03/2018</td><td>New drug criteria
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*