MEDICAL MUTUAL®

Drug Policy

Policy:	**201720- Global PA**	**Initial Effective Date: 04/20/2017**
Code(s):	**HCPCS J3490 and J3590**	**Annual Review Date: 05/17/2018**
SUBJECT:	**Cablivi (caplacizumab-yhdp)**	**Last Revised Date: 01/22/2019**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

The global prior approval policy requires prior approval for all new specialty drugs and new drugs with significant safety, clinical or potential abuse or diversion concerns filled under the medical benefit. The policy is intended to ensure that medications are used safely and will be effective for members.

POLICY STATEMENT

Prior approval is required for coverage of requested drug. Note: 1 month is equal to 30 days.

ASSESS THE FOLLOWING

- Indication
- Dose
- Contraindications
- Waste management: dosage units (vial/syringe size), NDC, number of units for dose
- Site of Care medical necessity criteria for the following agents:

PROCESS FOR EVALUATION AND DATA COLLECTION

1) Obtain patient's diagnosis and other patient and physician demographics, drug names, NDC for each drug if possible, dose, dosing interval/frequency, anticipated duration of therapy with this drug regimen, and start date.

2) Determine if patient is receiving these drugs as part of an investigational study. If so, determine if client's benefit coverage includes investigational use if the patient is enrolled in a clinical study.

Review case with Care Continuum physician for further review and analysis and consultation with an expert as needed. If needed, also review with the client the information available on the use of requested drug(s) for the individual patient to determine if coverage can be authorized.

3) Review FDA approved package insert for indication, dose, and contraindications.

4) Waste management. The dose is calculated and the number of vials/syringes needed to provide the dose is assessed. Determine appropriate number of dosage units (vials, syringes) for pre-certification. Provider should indicate the NDC for each drug. If the dose changes, re-evaluate number of vials/syringes needed.

5) If the nurse reviewer is unable to approve the indication, dose, or vial size, forward case to medical director for formal review. The prescribing physician may provide information to consider for further review such as a protocol approved by an investigational review board (IRB), abstracts from scientific meetings, etc.

6) If request is for a drug subject to site of care management, review the MMO site of care medical necessity criteria for initial therapy and reauthorizations.

MMO Site of Care Medical Necessity Criteria:

- Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

1. Age less than 18 years*; or
2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
3. History of a severe adverse event from previous administration of the prescribed medication; or
4. Requested medication is being administered as follows:
   - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
   - administered with dialysis; or
5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
[†]This criterion does not apply to Medicare or Medicare Advantage members.

Initial Approval/Extended Approval.

a) *Initial Approval.* Approve for 6 months.

b) *Extended Approval.* Approve for 6 months if the patient has had a beneficial response to treatment.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided, or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3490 and J3590

†**When *unclassified drug* (J3490) and *unclassified biologic* (J3590) are determined to be one of the medications listed within this policy.**

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics