INDICATIONS AND SELECTED IMPORTANT SAFETY INFORMATION

INDICATIONS:
CABLIVI (caplacizumab-yhdp) is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

CONTRAINDICATIONS:
CABLIVI is contraindicated in patients with a previous severe hypersensitivity reaction to caplacizumab-yhdp or to any of its excipients. Hypersensitivity reactions have included urticaria.

Please see accompanying Full Prescribing Information.
Coverage
Like other drugs, CABLIVI is expected to be bundled into inpatient payment rates (ie, MS-DRGs) when used in the hospital. The 3 MS-DRGs that represent the greatest number of potential patients who may be eligible for treatment involving CABLIVI are shown in the table below. This table may not be reflective of all MS-DRG codes that may be used for CABLIVI. The MS-DRG code is determined by the payer based on the primary diagnosis.

<table>
<thead>
<tr>
<th>Potential MS-DRGs</th>
<th>Connective Tissue Disorders with MCC</th>
<th>Connective Tissue Disorders with CC</th>
<th>Connective Tissue Disorders without CC/MCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>545</td>
<td>Connective Tissue Disorders with MCC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>546</td>
<td>Connective Tissue Disorders with CC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>547</td>
<td>Connective Tissue Disorders without CC/MCC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CMS has approved Cablivi’s application for a New Technology Add-on Payment (NTAP) for FY2020, effective October 1, 2019. The maximum NTAP for CABLIVI is $33,215 for FY2020. Specifically, if the cost of CABLIVI exceeds the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: 65% of the cost of CABLIVI or 65% of the amount by which the costs of the case exceed the standard DRG payment.²,³

Other Reimbursement Considerations
The specifics of coverage may vary by payer. Please refer to the individual patient’s plan to determine any applicable coverage requirements.

For patients covered by Medicare, drug costs for doses administered in the hospital are typically included in the MS-DRG payment and are covered under Medicare Part A. After inpatient discharge, most patients will self-administer CABLIVI at home; these drug costs are expected to be covered under the Medicare Part D (pharmacy) benefit.

SELECTED IMPORTANT SAFETY INFORMATION (con’t)

WARNINGS AND PRECAUTIONS:
Bleeding Risk:

- CABLIVI increases the risk of bleeding. In clinical studies, severe bleeding adverse reactions of epistaxis, gingival bleeding, upper gastrointestinal hemorrhage, and metronorrhagia were each reported in 1% of subjects. Overall, bleeding events occurred in approximately 58% of patients on CABLIVI versus 43% of patients on placebo. The risk of bleeding is increased, in patients with underlying coagulopathies and concomitant use of CABLIVI with drugs affecting hemostasis.

- If clinically significant bleeding occurs, interrupt use of CABLIVI. Von Willebrand factor concentrate may be administered to rapidly correct hemostasis. If CABLIVI is restarted, monitor closely for signs of bleeding.

- Withhold CABLIVI for 7 days prior to elective surgery, dental procedures or other invasive interventions. If emergency surgery is needed, the use of von Willebrand factor concentrate may be considered to correct hemostasis. After the risk of surgical bleeding has resolved, and CABLIVI is resumed, monitor closely for signs of bleeding.

Please see accompanying Full Prescribing Information.
ADVERSE REACTIONS:
The most common adverse reactions (>15% of patients) were epistaxis (29%), headache (21%) and gingival bleeding (16%).

CONCOMITANT USE OF ANTICOAGULANTS:
Concomitant use of CABLIWI with any anticoagulant may increase the risk of bleeding. Assess and monitor closely for bleeding with concomitant use.

PREGNANCY:
There are no available data on CABLIWI use in pregnant women to inform a drug associated risk of major birth defects and miscarriage.

• Fetal/neonatal adverse reactions: CABLIWI may increase the risk of bleeding in the fetus and neonate. Monitor neonates for bleeding.

• Maternal adverse reactions: All patients receiving CABLIWI, including pregnant women, are at risk for bleeding. Pregnant women receiving CABLIWI should be carefully monitored for evidence of excessive bleeding.

Please see accompanying Full Prescribing Information.
Please see accompanying Full Prescribing Information.