

Recommendation of the SEC (Renal) made in its 06th meeting held on 30.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	<p>e-Receipt No.: 80394 & No. 87012</p> <p>Eculizumab concentrate for solution for infusion 300 mg (10 mg/ml) [Soliris]</p>	<p>M/s. AstraZeneca Pharma India Limited</p>	<p>In light of the earlier SEC recommendations dated 21.05.2025, the firm presented the proposal for removal of condition No. 3 in the Marketing Authorisation of Eculizumab concentrate for solution for infusion 300 mg (10mg/ml) i.e., “Drug should be prescribed for the indication of Atypical hemolytic uremic syndrome (aHUS) based on the recommendations of Centre of Excellence (CoE) Institutions only”.</p> <p>After detailed deliberation, the committee recommended for the replacement of condition i.e., “Drug should be prescribed for the indication of Atypical hemolytic uremic syndrome (aHUS) based on the recommendations of Centre of Excellence (CoE) Institutions only” with “Drug should be prescribed for the indication of Atypical hemolytic uremic syndrome (aHUS) based on the recommendation of adult nephrologist or pediatric nephrologist only”.</p> <p>Further, the firm shall submit six monthly data on the drug usage in each patient, including proof of justified indication, appropriate vaccination, antibiotic prophylaxis and clinical outcome including infections to CDSCO. The data shall be put up in SEC for further evaluation.</p>