

eculizumab (SOLIRIS) per Solid Organ Transplant Clinical Practice Guidelines [3559]

Ordering restrictions for eculizumab (Soliris®):

1. Eculizumab (Soliris®) is restricted to attending-level physicians registered with the eculizumab (Soliris®) REMS Program
2. Patient must be registered with the manufacturer, Alexion Pharmaceuticals, Inc. to receive patient-specific doses for treatment
3. Indication must be FDA-approved (PNH or aHUS) or for transplant patients who meet criteria according to the solid organ transplant clinical practice guideline
4. Outpatient use when financial approval is obtained
5. Inpatient use for emergent care of newly diagnosed disease or continuation of maintenance therapy that is medically necessary

Medications

Refer to Transplant Center Clinical Practice Guidelines for Information on Indications & Dosing (Single Response)

() Induction at the time of transplant/Highly Sensitized Patient

[] eculizumab (SOLIRIS) infusion (RESTRICTED) (Single Response)

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| () POD 0: eculizumab (SOLIRIS) infusion (RESTRICTED) | intravenous, on call to O.R., Pre-op
POD 0: This medication is to be administered by Anesthesia. Administered in operating room / preop area and NOT the ICU. To be given UPON visualization for donor.
Are you an attending-level provider enrolled in the Soliris® REMS program?
Has the patient been provided medication counseling and a wallet card in accordance with the REMS program?
Indication: Solid Organ Transplant |
| () POD 1: eculizumab (SOLIRIS) infusion (RESTRICTED) | intravenous, once, For 1 Doses
POD 1
Are you an attending-level provider enrolled in the Soliris® REMS program?
Has the patient been provided medication counseling and a wallet card in accordance with the REMS program?
Indication: Solid Organ Transplant |
| () Weekly Dose: eculizumab (SOLIRIS) infusion (RESTRICTED) | intravenous, once, For 1 Doses
Weekly Dose
Are you an attending-level provider enrolled in the Soliris® REMS program?
Has the patient been provided medication counseling and a wallet card in accordance with the REMS program?
Indication: Solid Organ Transplant |
| () Supplemental Post-Plasmapheresis Dose: eculizumab (SOLIRIS) infusion (RESTRICTED) | 600 mg, intravenous, once, For 1 Doses
Supplemental Post-Plasmapheresis Dose: administer AFTER plasmapheresis.
Are you an attending-level provider enrolled in the Soliris® REMS program?
Has the patient been provided medication counseling and a wallet card in accordance with the REMS program?
Indication: Solid Organ Transplant |

[] Antimicrobial Prophylaxis Against Meningococcal Infection (Single Response)

If eculizumab (Soliris) is scheduled to be given LESS than two weeks after being vaccinated for meningococcal infection, please select antimicrobial prophylaxis to be administered in conjunction with vaccination.

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|--------------------------------------|---|
| () ciprofloxacin HCl (CIPRO) tablet | 500 mg, oral, 2 times daily
Reason for Therapy: |
| () ciprofloxacin (CIPRO) IV | 400 mg, intravenous, for 60 Minutes, 2 times daily
For eligible patients, this intravenous antimicrobial can be changed by pharmacists to oral ciprofloxacin per hospital policy.
Reason for Therapy: |

<input type="checkbox"/> penicillin v potassium (VEETID) tablet	500 mg, oral, 2 times daily Reason for Therapy:
<input type="checkbox"/> Vaccination against meningococcal infection required per REMS program if patient not previously vaccinated	
<input type="checkbox"/> meningococcal ACWY conjugate vaccine (Menveo) IM injection	0.5 mL, intramuscular, once, For 1 Doses
<input type="checkbox"/> Meningococcal Group B vaccine (BXSERO) 2-dose series	0.5 mL, intramuscular, once, For 1 Doses Give as a 2-dose series, with doses administered at least 1 month apart Bexsero (meningococcal group B vaccine) is given as a series of two vaccinations administered one month apart. Which dose is this? Indication for Therapy:
<input type="checkbox"/> Suspicion of Hyperacute Rejection/Antibody Mediated Rejection Treatment	
<input type="checkbox"/> eculizumab (SOLIRIS) infusion (RESTRICTED) (Single Response)	
<input type="checkbox"/> Weekly Dose: eculizumab (SOLIRIS) infusion (RESTRICTED)	intravenous, once, For 1 Doses Weekly Dose Are you an attending-level provider enrolled in the Soliris® REMS program? Has the patient been provided medication counseling and a wallet card in accordance with the REMS program? Indication: Solid Organ Transplant
<input type="checkbox"/> Supplemental Post-Plasmapheresis Dose: eculizumab (SOLIRIS) infusion (RESTRICTED)	600 mg, intravenous, once, For 1 Doses Supplemental Post-Plasmapheresis Dose: administer AFTER plasmapheresis. Are you an attending-level provider enrolled in the Soliris® REMS program? Has the patient been provided medication counseling and a wallet card in accordance with the REMS program? Indication: Solid Organ Transplant
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