aetna®

Soliris® (eculizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for Precertification Review.)

Aetna Precertification Notification
503 Sunport Lane, Orlando, FL 32809
Phone: 1-866-503-0857
FAX: 1-888-267-3277

For Medicare Advantage Part B:
FAX: 1-844-268-7263

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	E-mail:	

Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:		Last Name: *(Check One)*: ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.			
Address:		City:		State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:		Office Contact Name:		Phone:	

Specialty *(Check one)*: ☐ **Hematologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Mail Order
☐ Other: _____
Name: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for Soliris (eculizumab)**: Dose:** _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

For All Requests: (history of lab work MUST be submitted with request)

☐ Yes ☐ No Is the prescriber enrolled in the Soliris (eculizumab) Risk Evaluation and Mitigation Strategy (REMS) program?
☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?
→ ☐ Yes ☐ No Is the patient medically unstable for infusions at alternate levels of care?
☐ Yes ☐ No Does the patient have a clinical history of any cardiopulmonary conditions?
→ Please provide the description of the condition: _____
☐ Yes ☐ No Does this condition cause an increased risk of severe adverse reactions?
☐ Yes ☐ No Does the patient have documentation of unstable vascular access?
☐ Yes ☐ No Does the patient have physical or cognitive impairments such that home infusion would present an unnecessary health risk?
→ Please explain: _____
☐ Yes ☐ No Is there clinical evidence that the patient has an inability to safely tolerate intravenous volume load (including from unstable renal function)?
→ ☐ Yes ☐ No Is the inability to tolerate intravenous volume load due to unstable renal function?
→ Please document the following:
☐ GFR: _____ mL/min/1.73m^2 Date Collected: ____/____/____
☐ BUN: _____ mg/dL Date Collected: ____/____/____
☐ Creatinine: _____ mg/dL Date Collected: ____/____/____

Atypical hemolytic uremic syndrome (aHUS)

☐ Yes ☐ No Does the patient have unresolved serious Neisseria meningitis infection?

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G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

Generalized myasthenia gravis (gMG)

☐ Yes ☐ No Does the patient have a documented diagnosis of refractory generalized myasthenia gravis?

☐ Yes ☐ No Is the patient positive for anti-acetylcholine receptor (AchR) antibodies?

Please indicate the patient's Myasthenia Gravis Foundation of America (MGFA) Clinical classification:

Please select: ☐ Class I ☐ Class II ☐ Class III ☐ Class IV ☐ Class V

Please indicate the patient's Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score prior to initiation of therapy with Soliris (eculizumab): ☐ 0-5 MG-ADL ☐ 6-12 MG-ADL ☐ 13-18 MG-ADL ☐ 19-24 MG-ADL ☐ Unknown

☐ Yes ☐ No Has the patient had an ineffective response, intolerance or contraindication to immunosuppressants?

→ Please indicate the ***first*** medication that has been ineffective, not tolerated, or contraindicated:

☐ Azathioprine ☐ Chronic plasmapheresis ☐ Cyclophosphamide ☐ Cyclosporine
☐ Mycophenolate mofetil ☐ Methotrexate ☐ Tacrolimus ☐ None of the above

Was treatment ineffective, not tolerated, or contraindicated? ☐ ineffective ☐ not tolerated ☐ contraindicated

Please indicate the ***second*** medication that has been ineffective, not tolerated, or contraindicated:

☐ Azathioprine ☐ Chronic plasmapheresis ☐ Cyclophosphamide ☐ Cyclosporine
☐ Mycophenolate mofetil ☐ Methotrexate ☐ Tacrolimus ☐ None of the above

Was treatment ineffective, not tolerated, or contraindicated? ☐ ineffective ☐ not tolerated ☐ contraindicated

For how long did the patient receive treatment with the immunosuppressive agent(s) and/or plasmapheresis (either alone or in combination)?

Please indicate length of therapy: ☐ Less than 1 year ☐ 1 year or longer

Paroxysmal nocturnal hemoglobinuria (PNH)

☐ Yes ☐ No Has the patient had a flow cytometric analysis completed?

→ Please provide the percentage of PNH type III red cells: _____%

☐ Yes ☐ No Did the flow cytometric analysis indicate the percentage of glycosylphosphatidylinositol- anchored proteins (GPI- AP) deficient poly-morphonuclear cells (PMNs)?

→ Please provide the percentage of GPI- anchored proteins PMNs: _____%

☐ Yes ☐ No Does the patient have a documented history of major adverse vascular events (MAVE) from thromboembolism?

→ ☐ Yes ☐ No Is the patient transfusion dependent?

→ Please indicate the patient's platelet count and date **prior to initiation** of treatment with Soliris (eculizumab)

Result: _____mL Date: _____/_____/_____

Please provide the date of the last transfusion: _____/_____/_____

Provide the hemoglobin result **prior to the initiation** of Soliris (eculizumab) and date obtained

Result: _____g/dL Date: _____/_____/_____

→ ☐ Yes ☐ No Prior to the transfusion, did the patient have symptoms of anemia?

Please indicate the type of MAVE and check all that apply:

Venous thrombosis

- ☐ Acute peripheral vascular occlusion
- ☐ Thrombophlebitis
- ☐ Deep vein thrombosis
- ☐ Hepatic/ portal vein thrombosis
- ☐ Mesenteric/ splenic vein thrombosis
- ☐ Pulmonary embolus
- ☐ Renal vein thrombosis
- ☐ Clinically apparent distal embolization (e.g., lower extremity ulceration, tissue necrosis, gangrene, limb amputation or other end-organ damage)
- ☐ Other – please explain: _____

Arterial thrombosis

- ☐ Cerebrovascular accident
- ☐ Myocardial infarction
- ☐ Transient ischemic attack
- ☐ Unstable angina
- ☐ Other – please explain: _____

☐ Yes ☐ No ☐ Unknown Does the patient have severe aplastic anemia (AA)?

→ ☐ Yes ☐ No Has the patient had a bone marrow biopsy?

→ **Please select result:**

☐ Showing less than 25% of normal cellularity
☐ Showing less than 50% normal cellularity with fewer than 30% of the cells are hematopoietic

Please indicate all that apply to the patient:

☐ Absolute reticulocyte count less than 40,000/microliter
☐ Absolute neutrophil count (ANC) less than 500/ microliter
☐ Platelet count less than 20,000/ microliter
☐ None of the above

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For All Continuation Requests: (history of lab work MUST be submitted with request)

Please indicate the length of time on Soliris (eculizumab) therapy: _____

☐ Yes ☐ No Is this continuation request a result of the patient receiving samples of Soliris (eculizumab)? (Sampling of Soliris (eculizumab) does not guarantee coverage under the provisions of the pharmacy benefit)

☐ Yes ☐ No Has the patient received Soliris (eculizumab) within the past 6 months?

→ ☐ Yes ☐ No Does the patient have a documented severe and/or potentially life threatening adverse event that occurred during or following the previous infusion?

→ ☐ Yes ☐ No Could the adverse reaction be managed through pre-medication in the home or office setting?

Atypical hemolytic uremic syndrome (aHUS)

Please document the following:

Baseline platelet count: _____ mcL Date Collected: ____/____/____

Current platelet count: _____ mcL Date Collected: ____/____/____

Current lactic acid dehydrogenase (LDH) level: _____U/L Date Collected: ____/____/____

Baseline serum creatinine level: _____mg/dL Date Collected: ____/____/____

Current serum creatinine level: _____mg/dL Date Collected: ____/____/____

☐ Yes ☐ No Is there clinical evidence that the patient had a reduction in signs of complement-mediated Thrombotic microangiopathy (TMA)?

→ Please indicate which of the following apply to the patient:

- ☐ Complete TMA response (hematologic normalization plus at least 25% reduction in serum creatinine for at least 4 weeks)
- ☐ Hematologic normalization (maintenance of normal platelet counts and LDH levels for at least 4 weeks)
- ☐ Platelet count change from baseline
- ☐ Reduction in the daily TMA intervention rate (defined as the number of plasma exchange or plasma infusion interventions and the number of new dialysis required per patient per day)
- ☐ TMA-event free status (absence for at least 12 weeks of a decrease in platelet count of greater than 25% from baseline, treatment with plasma exchange or plasma infusion, or new dialysis requirement)
- ☐ None of the above

Generalized myasthenia gravis (gMG)

Please indicate the patient's Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score prior to initiation of therapy with Soliris (eculizumab): _____

What is the patient's current Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score? _____

☐ Yes ☐ No Has the patient demonstrated a clinically meaningful response regarding daily activities as measured by an improvement in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score from baseline?

→ Please indicate the patient's improvement in the MG-ADL total score from baseline: _____ points

Paroxysmal nocturnal hemoglobinuria (PNH)

☐ Yes ☐ No Has the patient had a reduction in intravascular hemolysis as measured by a stabilization of hemoglobin levels?

→ Please provide the baseline hemoglobin and date obtained: Result: _____g/dL Date: ____/____/____

Please provide the current hemoglobin and date obtained: Result: _____g/dL Date: ____/____/____

☐ Yes ☐ No Does the patient have stabilized hemoglobin levels?

☐ Yes ☐ No Has the patient had a reduction in transfusions from baseline at initiation?

H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required):* _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.