

ULTOMIRIS MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ DOB _____

Patient's height in feet and inches _____ Patient's weight in pounds _____

■ Diagnosis

- D59.5 Paroxysmal nocturnal hemoglobinuria. [Marchiafava-Micheli] G70.00 Myasthenia gravis without (acute) exacerbation
 D59.3 Hemolytic-uremic syndrome G70.01 Myasthenia gravis with (acute) exacerbation
 G36.0 Neuromyelitis Optica

■ Details Needed for Approval

For all cases: Has the patient obtained the meningococcal vaccine? _____ If not, please document rationale and/or vaccination plan.

For paroxysmal nocturnal hemoglobinuria (PNH):

- If the patient has PNH, provide results of PNH clone detection by flow cytometry, and baseline values of one or more of the following tests: Serum LDH, hemoglobin level, and packed RBC transfusion requirements.
- Circle the appropriate indication(s) for this patient's therapy: a) thrombotic event b) organ damage secondary to chronic hemolysis c) patient is pregnant and potential benefit outweighs potential fetal risk d) patient is transfusion dependent e) patient has high LDH with clinical symptoms
- Does the patient have failure on or contraindication to Soliris (eculizumab)? _____

For atypical hemolytic uremic syndrome (aHUS):

- Have you ruled out STEC-HUS, typical HUS, and infection related HUS? _____
- Have you ruled out coexisting diseases or conditions, S. pneumonia, Influenza A H1N1 or cobalamin deficiency? _____
- Have you ruled out thrombocytopenic purpura (TTP)? _____
- Provide baseline values of the following: LDH, serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement.
- Does the patient have failure on or contraindication to Soliris (eculizumab)? _____

For AchR AB+ generalized myasthenia gravis (gMG):

- Does the patient have MGFA Clinical Classification of Class II to Class IV? _____ If yes, what is the Classification? _____
- Provide assessment of the baseline Quantitative Myasthenia Gravis (QMG) score and lab results for position anti-AChR antibodies.
- Does the patient have an MG-ADL total score of ≥ 6 ? _____ If yes, what is the score? _____
- Has the patient failed treatment over at least 1 year with at least 2 immunosuppressive therapies, or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)? _____

For Neuromyelitis Optica (NMOSD):

- Medical records including detailed documentation of NMOSD clinical characteristics.
- Hepatitis B surface antigen and Hepatitis B core total antibody results from the past two months.
- Negative TB test (QFT, PPT or Spot TB) from the past two months.
- Serum immunoglobulin levels and AQP4 positive antibody lab results.
- Will the patient concurrently be treated with complement inhibitors (such as Soliris) or Anti-IL6 therapy (such as Actemra)? _____
- If the patient has been on IVIG therapy when was the last treatment? _____ Rituximab? _____
- How many episodes of relapse requiring rescue therapy has the patient had in the past two years? _____
- Please include the patient's EDSS score. (Often a score of ≤ 7.5 is required by insurance carriers for approval.)

■ Ultomiris (ravulizumab) Medication Order

- Loading dose, _____ mg.
 If the patient is transitioning from eculizumab, loading dose is administered 2 weeks after last eculizumab, which was given on date _____.
- Maintenance dose, _____ mg every _____ weeks for 1 year, starting 2 weeks after the loading dose.

Administer over one hour in adults. Follow manufacturer's instructions.

■ Rescue Management in case of Infusion Therapy Reaction

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Stop medication infusion and start normal saline infusion at 50 ml/hr. Call ordering provider to report reaction.
- Follow standing reaction orders, including Diphenhydramine, Methylprednisolone, Albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen or equivalent and call 911. Repeat if severe symptoms persist.

■ Ordering Provider Authorization

Provider Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ Indiv. NPI #: _____ License: _____

Best Contact Person in Office: _____ Direct Phone to Contact Person: _____

Please include patient demographics and insurance, including card scans, most recent chart note, all relevant scans and tests, and last H&P.

FAX THIS ORDER AND SUPPORTING DOCUMENTATION TO 201-266-0437 OR UPLOAD USING YOUR SECURE DEDICATED WEBPAGE – TO GET A PERSONAL LINK PLEASE CONTACT THE INTAKE TEAM.