

For **reauthorization**:

1. Chart notes must demonstrate hematologic normalization as evidenced by increased platelet count or LDH maintained below upper limit of normal; AND
2. Improved or preserved kidney function.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

For **initial** authorization:

1. Medication is prescribed by or in consultation with a hematologist; AND
2. Member has a documented diagnosis of PNH as confirmed by flow cytometry; AND
3. Member has a lactate dehydrogenase (LDH) level $>1.5x$ upper limit of normal (ULN); AND
4. Member has at least one PNH-related G(I reW*n9T/F2 11.4Tf1 0 0 1 2219.675 442.05 526.28 180.1

For **reauthorization**:

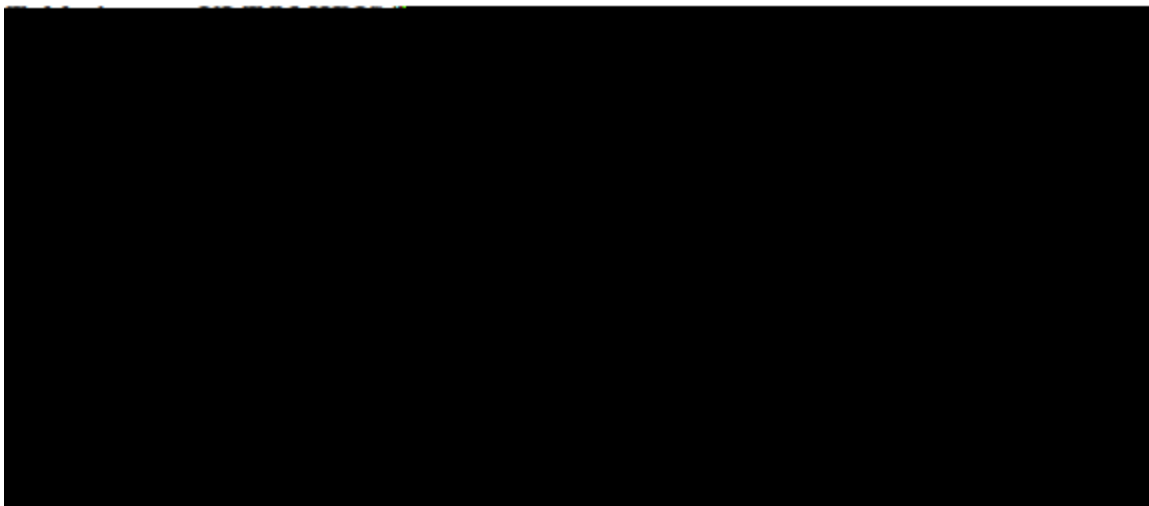
1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ultomiris (ravulizumab-cwvz) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/07/2019	New policy for Ultomiris created.
10/26/2019	New diagnosis of aHUS added.
06/03/2021	aHUS: Updated references. Added specialist requirement. Revised diagnostic parameters. Summarized excluded causes. Removed list of restrictions from clinical trials. Revised renewal criteria. PNH: Updated references. Removed nephrology as specialist. Removed transfusion and organ damage requirements. Updated dosing information. Reduced initial approval duration from 12 months to 6 months. Revised renewal criteria.
05/19/2022	Diagnosis of myasthenia gravis added.
08/12/2022	Added dosing for new subQ product (adults with PNH or aHUS only); added pharmacy benefit.
07/19/2023	gMG: Added reference. Split list of conventional drug trials. Added trial of Vyvgart IV. aHUS: Updated and added references. Corrected ADAMTS13 level cutoff. Changed "evidence of hemolysis" to evidence of MAHA. PNH: Added reference. Added that they must be symptomatic.
01/25/24	Approved by ODM

APPENDIX 1:



APPENDIX 2:

MG Foundation of America (MGFA) Clinical Classification	
Class I	any ocular weakness; all other muscle strength is normal

20. Meisel A, Annane D, Vu T, et al. Long-term efficacy and safety of r/F2 10.4 Tf1 0 0 1 518(n)18(e)A(o)18(n)18(A)-2zoln