Eculizumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guideline:
Daman	Pharmacy Standards & Governance	N/A

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1. Abstract

1.1 For Members

Eculizumab is an injectable prescription medicine administered intravenously to treat paroxysmal nocturnal hemoglobinuria, generalized myasthenia gravis, and neuromyelitis Optica spectrum disorder in adult patients. It is also used to treat atypical hemolytic uremic syndrome in both pediatric and adult patients.

1.2 For Medical Professionals

Eculizumab is a recombinant monoclonal antibody administered intravenously to inhibit terminal complement activation at C5 protein and thereby reduces hemolysis and thrombotic microangiopathy.

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Eculizumab. It also highlights the medical criteria for coverage.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Medical Indications:

Eculizumab is an injectable prescription medicine for intravenous use, a recombinant monoclonal antibody, inhibits terminal complement activation at the C5 protein and thereby reduces hemolysis and thrombotic microangiopathy. It is indicated for the treatment of:

1. **Paroxysmal Nocturnal Hemoglobinuria** (**PNH**): reduces hemolysis in adult patients particularly in those with a history of blood transfusions.
2. **Atypical Hemolytic Uremic Syndrome** (**aHUS**): inhibits complement-mediated thrombotic microangiopathy in adult patients and for patients less than 18 years of age, dosage is calculated according to body weight. Eculizumab has a limited use, where it's NOT indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
3. **Generalized Myasthenia Gravis** (**gMG**): indicated in adult patients who are ant acetylcholine receptor (AchR) antibody positive.
4. **Neuromyelitis Optica Spectrum Disorder** (**NMOSD**): indicated in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Dosage and Administration:

1. **Paroxysmal Nocturnal Hemoglobinuria** (**PNH**):

Recommended dosage regimen for adult patients (18 years of age and older), consists of:

Adult regimen for PNH
600 mg weekly for the first 4 weeks, followed by
900 mg for the fifth dose 1 week later, then
900 mg every 2 weeks thereafter

2. **Atypical Hemolytic Uremic Syndrome** (**aHUS**):

Recommended dosage regimen for adult patients (18 years of age and older), consists of:

Adult regimen for aHUS
900 mg weekly for the first 4 weeks, followed by
1200 mg for the fifth dose 1 week later, then
1200 mg every 2 weeks thereafter

Recommended dosage regimen for pediatric patients (younger than 18 years of age) based upon body weight, according to the following table:

Pediatric regimen for aHUS		
Patient Body Weight	Induction	Maintenance
40 kg and over	900 mg weekly x 4 doses	1200 mg at week 5; then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly x 2 doses	900 mg at week 3; then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly x 2 doses	600 mg at week 3; then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 3 weeks

3. **Generalized Myasthenia Gravis** (**gMG**) and **Neuromyelitis Optica Spectrum Disorder** (**NMOSD**):

Recommended dosage regimen for adult patients (18 years of age and older), consists of:

Adult regimen for gMG and NMOSD
900 mg weekly for the first 4 weeks, followed by
1200 mg for the fifth dose 1 week later, then
1200 mg every 2 weeks thereafter

Dose Adjustment:

For adult and pediatric patients with aHUS, and adult patients with gMG or NMOSD, supplemental dosing of Eculizumab is required in the setting of concomitant plasmapheresis or plasma exchange (PE), or fresh frozen plasma infusion (PI) as the shown in table below:

Type of Plasma Intervention	Most Recent Eculizumab Dose	Supplemental Eculizumab Dose with Each Plasma Intervention	Timing of Supplemental Eculizumab Dose
Plasmapheresis or plasma exchange (PE)	300 mg	300 mg per each plasmapheresis or plasma exchange session	Within 60 minutes after each plasmapheresis or plasma exchange
	≥600 mg	600 mg per each plasmapheresis or plasma exchange session	
Fresh frozen plasma infusion (PI)	≥300 mg	300 mg per infusion of fresh frozen plasma	60 minutes prior to each infusion of fresh frozen plasma

Pediatric Uses:

- PNH, gMG, and NMOSD: safety and effectiveness of Eculizumab in pediatric patients have not been established.
- aHUS: the safety and effectiveness of Eculizumab have been established in pediatric patients from ages 1 month to 17 years.

Vaccination Prior to Treatment:

Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment.
Recommended vaccination and prophylaxis for patients undertaking Eculizumab therapy to reduce the risk of serious infections e.g., meningococcal infections (Neisseria meningitidis).
Provide two weeks of antibacterial drug prophylaxis to patients if Eculizumab must be initiated

immediately and vaccines (meningococcal vaccines) are administered less than two weeks before starting Eculizumab therapy.

Eligible clinical specialties

Eligible clinical specialities
Hematologist
Neurologist
Ophthalmologist
Internal medicine

3.2 Requirements for Coverage

Failure to submit, upon request or when requesting a clinical history, an indication and the need for testing will result in the rejection of the claim.

3.3 Non-Coverage

- Eculizumab is not covered when the above criteria are not met.
- Coverage as per member SOB

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

4. Denial Codes

DOH denial codes with description are elaborated for reference. These are specialized codes directed by DOH, that explains the reason of rejection of the service by DAMAN to the providers

Code	Code Description
MNEC 004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician's specialty
NCOV-003	Service(s) is (are) not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125166s434lbl.pdf
https://alexion.com/en/our-medicines/medicines/soliris
BNF 81 (British National Formulary) March 2021, pg. 1064-1065
Pre Approval Form Link

5.2 Revision History

Date	Version No.	Change(s)
05.04.2024	V1.0	New Version
11.11.2024	V2.0	No changes / updated in new format