Actor portrayal

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

Start or switch your adult patients to ULTOMIRIS®

- ULTOMIRIS is the #1 prescribed treatment for patients with atypical-HUS[1,2]*
- Demonstrated efficacy and safety in clinical trials[1,3]†
- Preferred by adult patients[4‡]

*ULTOMIRIS had more than a 50% share of patients with atypical-HUS actively taking medications every month from April 2022 through October 2025.[2]
†A Phase 3, single-arm, global clinical trial evaluating the efficacy and safety of ULTOMIRIS in adult patients with atypical-HUS (N=58) over an initial 26-week evaluation period, followed by a 4.5-year extension period.[1,3]
‡A web-based survey of US adults (N=50) with a confirmed diagnosis of atypical-HUS who had previously received eculizumab and ≥3 doses of ULTOMIRIS.[4]
HUS=hemolytic uremic syndrome.

Have questions?
Talk to your atypical-HUS representative

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [*see Warnings and Precautions (5.1)*] Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.
- Patients receiving ULTOMIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS [*see Warnings and Precautions (5.2)*].

INDICATION

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Limitation of Use:
ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Please see additional Important Safety Information throughout and the Patient Information and Instructions for Use in the full Prescribing Information (UltomirisHCP.com/PI) for ULTOMIRIS (ravulizumab), including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, or scan the QR code.

Business card holder

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

ULTOMIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ULTOMIRIS. The benefits and risks of treatment with ULTOMIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

What can you potentially expect to see in your adult patients with atypical-HUS treated with ULTOMIRIS®?*

- Complete TMA response[1,3,5†]
- Normalization of hematologic parameters (platelet count and LDH) and improvement in renal (SCr) parameters[1,3,5†]
- Possibility of dialysis discontinuation[1,3,5‡]
- Improvement in renal function (eGFR)[1,3,5§]

*Based on data from a Phase 3, single-arm, global clinical trial evaluating the efficacy and safety of ULTOMIRIS in adult patients with atypical-HUS (N=58) over an initial 26-week evaluation period, followed by a 4.5-year extension period.[1,3]

†Primary endpoint. Complete TMA response was defined as normalization of hematologic parameters (platelet count and LDH) and ≥25% improvement in SCr from baseline during the 26-week initial evaluation period. Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and for any measurement in between.[1]

‡In the 311 study, dialysis requirement status was a secondary endpoint.[1] Among the adult patients who received dialysis at baseline (n=29/56), 59% (n=17/29) had discontinued dialysis by Week 26 and 67% (n=12/18) by Year 2.[3,5] Six of 27 (22%) patients who were off dialysis at baseline were on dialysis by Week 26.[1] Four of 20 (20%) patients who were available at the Year 2 visit had initiated dialysis.[6] Please see further information on page 6.

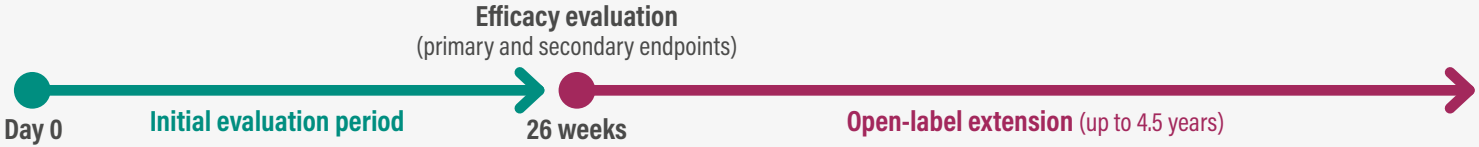
§In the 311 study, change in eGFR was a secondary endpoint.[1] Please see further information on page 8.

eGFR=estimated glomerular filtration rate; HUS=hemolytic uremic syndrome; LDH=lactate dehydrogenase; SCr=serum creatinine; TMA=thrombotic microangiopathy.

Please see additional Important Safety Information throughout and the accompanying Patient Information and Instructions for Use in the full Prescribing Information (UltomirisHCP.com/PI) for ULTOMIRIS (ravulizumab), including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, or scan the QR code on Page 1.

ULTOMIRIS® was studied in critically ill* adult patients in the 311 study[1,3]

Study 311: Phase 3, 26-week, open-label, single-arm study of complement inhibitor–naïve adult patients (≥18 years old and ≥40 kg; N=56)[1,3]



Clinical trial criteria

Select inclusion criteria[1]:

- Platelet count ≤150 x 10^9/L
- Evidence of hemolysis such as an elevation in serum LDH
- SCr above the ULN or required dialysis

Select exclusion criteria:

- Patients with TMA due to ADAMTS13 deficiency, STEC-HUS, or genetic defect in cobalamin C metabolism[1]
- Patients receiving prior PE/PI for ≥28 days before screening[3]
- Patients on chronic dialysis[3†]

Efficacy evaluation[1]

Primary endpoint: complete TMA response (at 26 weeks), which comprised of[‡]:

Hematologic parameters

- Platelet count normalization (≥150 x 10^9/L)[3]
- Serum LDH normalization (≤246 U/L)[3]

Renal parameters

- ≥25% improvement in SCr from baseline

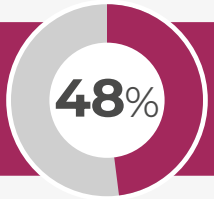
Secondary endpoints[1,3]:

- Time to complete TMA response
- Dialysis requirement
- Change in eGFR
- eGFR category stage change
- Change in hematologic variables (platelets, LDH, and hemoglobin)

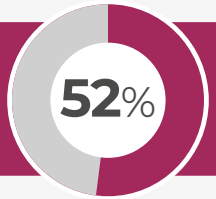
*Defined as receiving ICU-level care.[2]
†Defined as dialysis on a regular basis for ESKD.[3]
‡Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and for any measurement in between.[1]

ADAMTS13=a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13; eGFR=estimated glomerular filtration rate; ESKD=end-stage kidney disease; ICU=intensive care unit; LDH=lactate dehydrogenase; PE=plasma exchange; PI=plasma infusion; SCr=serum creatinine; STEC-HUS=Shiga toxin–producing *Escherichia coli* hemolytic uremic syndrome; TMA=thrombotic microangiopathy; ULN=upper limit of normal.

Select baseline characteristics and lab values

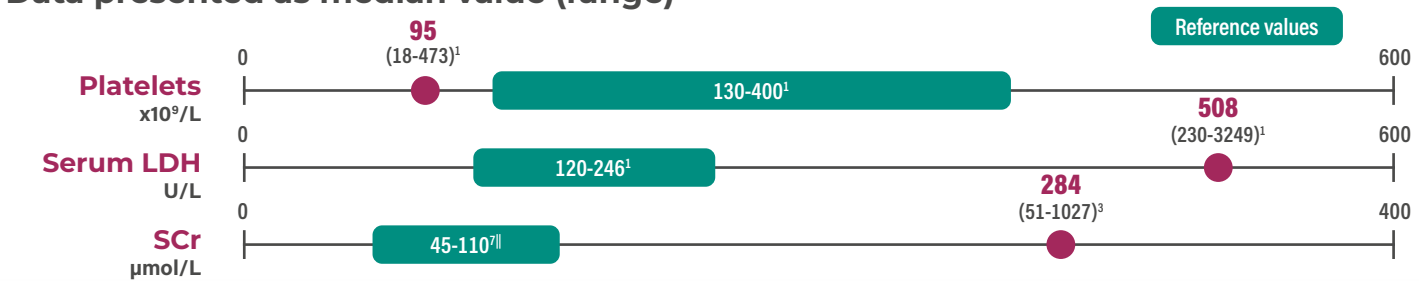


(27/56) were critically ill, defined as receiving ICU-level care[3]



(29/56) were on dialysis within 5 days of ULTOMIRIS initiation[1]

Data presented as median value (range)§



§Baseline values may be after PE/PI in some patients.[3]
‖60-110 µmol/L for men and 45-90 µmol/L for women.[7]

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS.

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with the REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ULTOMIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently, and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of ULTOMIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card at all times during and for 8 months following ULTOMIRIS treatment.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

Achieve complete TMA response in your patients[1]*

Proportion of patients who achieved:		26 weeks (~6 months)[1]	1 year[2]	2 years[5]
Complete TMA response*		**54%** (n=30/56) 95% CI: 40%-67% Primary endpoint	**61%** (n=34/56) 95% CI: 47%-74%	**61%** (n=34/56) 95% CI: 47%-74%
Hematologic parameters	Platelet count normalization	**84%** (n=47/56)	**86%** (n=48/56)	**86%** (n=48/56)
	LDH normalization	**77%** (n=43/56)	**84%** (n=47/56)	**88%** (n=49/56)
Renal parameters	≥25% improvement in SCr	**59%** (n=33/56)	**63%** (n=35/56)	**63%** (n=35/56)

Complete TMA response* was achieved at a median time of 86 days (range: 7 to 169 days) during the initial evaluation period[1†]

ULTOMIRIS® treatment of atypical-HUS should be a minimum duration of 6 months. Due to the heterogeneous nature of atypical-HUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized.[1]

*Complete TMA response was defined as normalization of hematologic parameters (platelet count and LDH) and ≥25% improvement in SCr from baseline. Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and for any measurement in between.[1]

†Secondary endpoint.[3]

BL=baseline; CI=confidence interval; HUS=hemolytic uremic syndrome; LDH=lactate dehydrogenase; SCr=serum creatinine; TMA=thrombotic microangiopathy.

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Give your patients the chance to improve hematologic parameters[1]

ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

Mean platelet count over time[3†]

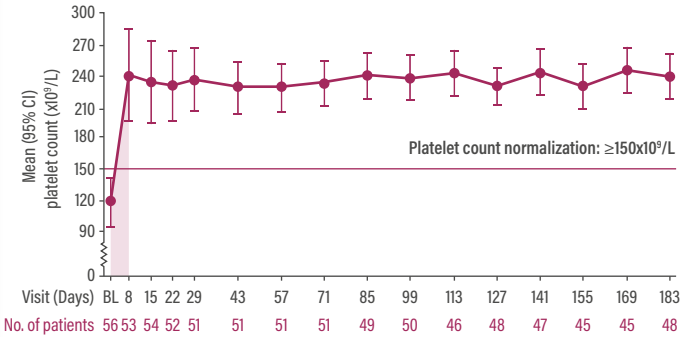


Figure adapted from Rondeau E, et al. 2020

Mean LDH levels over time[3†]

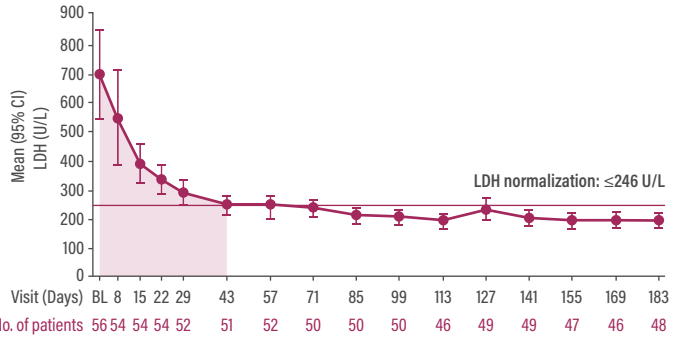


Figure adapted from Rondeau E, et al. 2020

ULTOMIRIS led to the rapid doubling of platelets by Day 8[1]

LDH normalization for the majority of patients (53%, 28/53) by Day 43[2]

†Secondary endpoint.[3]

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

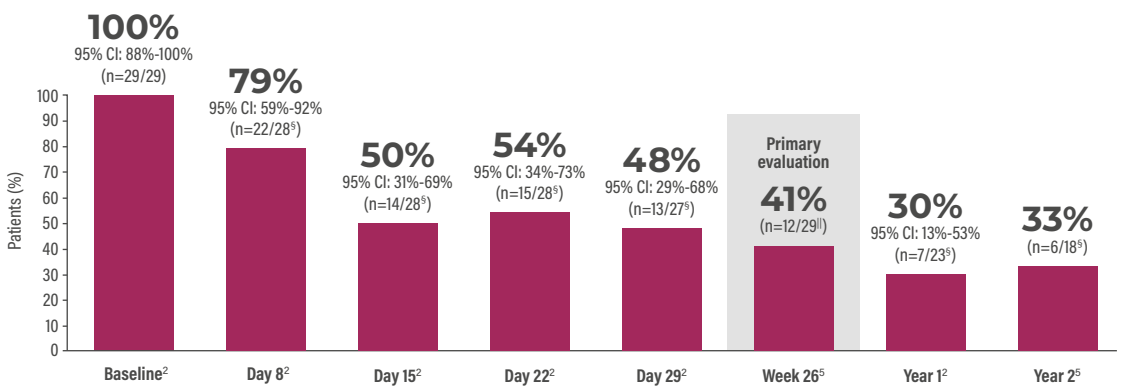
Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

ULTOMIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Children treated with ULTOMIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Give your patients the chance to discontinue dialysis[1*†]

Proportion of adult patients who were on dialysis at baseline (29/56[‡]) and remained on dialysis through 2 years[2,5]



Most patients (59% [17/29]) receiving dialysis at baseline discontinued dialysis by 26 weeks (~6 months)[1]

Six of the 27 patients who were not on dialysis at baseline were on dialysis at 26 weeks[1]

Of patients who were available at 2 years, 4 out of 20 initiated dialysis[6]

ULTOMIRIS® treatment of atypical-HUS should be a minimum duration of 6 months. Due to the heterogeneous nature of atypical-HUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized.[1]

*Secondary endpoint.[1]

†Patients on chronic dialysis at screening (defined as dialysis on a regular basis for ESKD) were excluded from the study.[3]

‡Within 5 days of ULTOMIRIS initiation.[3]

§Denominator represents the number of patients available at each visit.[2]

‖Denominator represents the total number of patients on dialysis at the beginning of the study and included in the efficacy analysis.[5]

CKD=chronic kidney disease; CI=confidence interval; eGFR=estimated glomerular filtration rate; ESKD=end-stage kidney disease; HUS=hemolytic uremic syndrome; KDIGO=Kidney Disease: Improving Global Outcomes.

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Give your patients the chance to improve kidney function[1*†]

ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

Mean changes in eGFR for all patients in the initial evaluation period and through 2 years[5*]

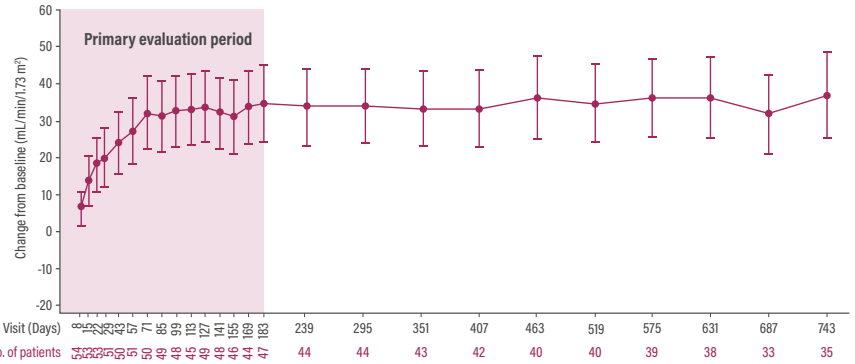

Figure adapted from Dixon BP, et al. 2024

At baseline, there were 13 patients with eGFR ≥15[3¶]

Of these patients at 26 weeks:

- 85% (11/13) maintained or improved their eGFR category
- 15% (2/13) declined despite treatment with ULTOMIRIS—specifically, 2 patients went from eGFR 15-29 to eGFR <15

At baseline, there were 34 patients with eGFR <15 (including patients receiving dialysis)[3‡¶]

Of these patients at 26 weeks:

- 68% (23/34) saw an improvement in ≥1 eGFR category, and 52% (12/23) of those who improved progressed to eGFR ≥60

Most patients maintained or improved kidney function (n=45/47) by 26 weeks (~6 months)[3¶]

*Secondary endpoint.[1] †Patients on chronic dialysis at screening (defined as dialysis on a regular basis for ESKD) were excluded from the study.[3] ‡Within 5 days of ULTOMIRIS initiation.[3] ¶eGFR categories were classified based on KDIGO guidelines. eGFR values were: Category 1=≥90; Category 2=60 to 89; Category 3A=45 to 59; Category 3B=30 to 44; Category 4=15 to 29; Category 5=<15 (including dialysis).[8,9] In the 311 clinical trial, CKD staging was defined by eGFR at a certain point in time. Because CKD is defined by KDIGO guidelines as abnormalities in kidney structure or function, such as low eGFR, present for a minimum of 3 months, eGFR categorization was deemed more appropriate. Stage 5 CKD is unlikely to improve.[8,9]

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation

ULTOMIRIS treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized. There are no specific data on ULTOMIRIS discontinuation. After discontinuing treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months. TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure. In addition, at least two of the following laboratory signs observed concurrently and results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

Safety profile of ULTOMIRIS® in adult patients with atypical-HUS

Adverse reactions reported in ≥10% of ULTOMIRIS-treated adult patients with atypical-HUS at 26 weeks[1]

Body System	Adverse Reaction	Adult Patients (N=58)	
		All Grades* (n=53), n (%)	≥Grade 3 (n=14), n (%)
Blood and lymphatic system disorders	Anemia	8 (14)	0 (0)
Gastrointestinal disorders	Diarrhea	18 (31)	2 (3)
	Nausea	15 (26)	2 (3)
	Vomiting	15 (26)	2 (3)
	Constipation	8 (14)	1 (2)
	Abdominal pain	7 (12)	1 (2)
General disorders and administration site conditions	Pyrexia	11 (19)	1 (2)
	Edema peripheral	10 (17)	0 (0)
	Fatigue	8 (14)	0 (0)
Infections and infestations	Upper respiratory tract infection†	15 (26)	0 (0)
	Urinary tract infection	10 (17)	5 (9)
	Gastrointestinal infection‡	8 (14)	2 (3)
Metabolism and nutrition disorders	Hypokalemia	6 (10)	1 (2)
Musculoskeletal and connective tissue disorders	Arthralgia	13 (22)	0 (0)
	Back pain	7 (12)	1 (2)
	Muscle spasms	6 (10)	0 (0)
	Pain in extremity	6 (10)	0 (0)
Nervous system disorders	Headache	23 (40)	1 (2)
Psychiatric disorders	Anxiety	8 (14)	1 (2)
Respiratory, thoracic, and mediastinal disorders	Cough	10 (17)	0 (0)
	Dyspnea	10 (17)	1 (2)
Skin and subcutaneous tissue disorders	Alopecia	6 (10)	0 (0)
	Dry skin	6 (10)	0 (0)
Vascular disorders	Hypertension	14 (24)	7 (12)

*Graded per CTCAE v5.0.[1]
†Grouped term includes nasopharyngitis, pharyngitis, upper respiratory tract infection, rhinitis, viral upper respiratory tract infection, rhinovirus infection, viral pharyngitis, rhinorrhea, and oropharyngeal pain.[1]
‡Grouped term includes gastroenteritis, gastrointestinal infection, enterocolitis infectious, infectious colitis, and enterocolitis.[1]
C5i=complement 5 inhibitor; CTCAE=Common Terminology Criteria for Adverse Events; HUS=hemolytic uremic syndrome; STEC-HUS=Shiga toxin–producing *Escherichia coli* hemolytic uremic syndrome.

The most frequent adverse reactions reported in ≥20% of patients in the initial evaluation were headache, diarrhea, nausea, vomiting, upper respiratory tract infection,† hypertension, and pyrexia.[1]

Four patients died during the adult atypical-HUS study. Patient deaths were determined by study investigators as unrelated to study drug; the cause of death was sepsis in 2 patients and intracranial hemorrhage in 1 patient. The fourth patient, who was discontinued per protocol from the trial after a diagnosis of STEC-HUS, died due to pretreatment cerebral arterial thrombosis.[3]

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Long-term safety profile of ULTOMIRIS in adult patients with atypical-HUS

ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

Most common adverse events reported in ≥15% of ULTOMIRIS-treated adult patients with atypical-HUS through a 2-year follow-up[6]

Adverse Events	Adult Patients Naïve to C5i Treatment (N=58), n (%)
Headache	23 (40)
Diarrhea	20 (35)
Nausea	17 (29)
Vomiting	17 (29)
Arthralgia	16 (28)
Hypertension	14 (24)
Dyspnea	12 (21)
Pyrexia	12 (21)
Urinary tract infection	11 (19)
Anemia	10 (17)
Cough	10 (17)
Peripheral edema	10 (17)
Constipation	9 (16)
Fatigue	9 (16)
Nasopharyngitis	9 (16)

No unexpected safety signals were observed between 26-week and 2-year data[1,3,5]

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Thromboembolic Event Management
The effect of withdrawal of anticoagulant therapy during treatment with ULTOMIRIS has not been established. Treatment should not alter anticoagulant management.

Infusion-Related Reactions
Administration of ULTOMIRIS may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions.

In clinical trials, infusion-related reactions occurred in approximately 1 to 7% of patients, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste). These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS and institute appropriate supportive measures.

Real-world effectiveness of ULTOMIRIS® was assessed among atypical-HUS patients who switched within 3 months of eculizumab treatment[10]

A physician panel–based chart review study: methods

Study design

Analysis set: n=36

Study objective: to assess the real-world effectiveness of switching to ULTOMIRIS following short-term eculizumab treatment (within 3 months).

Methods: a retrospective, longitudinal, physician panel–based chart review of adults with atypical-HUS in the US who switched from eculizumab to ULTOMIRIS within 3 months of eculizumab initiation between November 2019 and September 2022. In order to be included in the review, physicians must have 1 or more patients with atypical-HUS and with medical and laboratory records. Up to 5 patients were randomly selected who had 6 months or more of medical records following initiation of ULTOMIRIS.

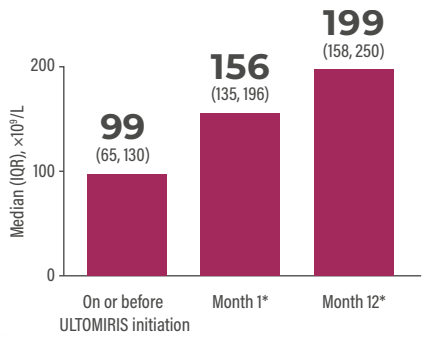
Design: laboratory parameters (platelet count, LDH levels, and SCr levels) were collected at the index date or at the point closest to the index date within the prior 6 months and at 1, 3, 6, and 12 months after the index date. Complete TMA response was defined as having platelet count normalization (≥150×10^9/L), LDH normalization (≤246 U/L), and ≥25% reduction in SCr levels compared with the last measure before eculizumab treatment and was determined based on laboratory data or physician-reported complete TMA response.

Note: Data are from an abstract. **Limitations to the study were not disclosed.**
CI=confidence interval; HUS=hemolytic uremic syndrome; IQR=interquartile range; LDH=lactate dehydrogenase; SCr=serum creatinine; SD=standard deviation; TMA=thrombotic microangiopathy.

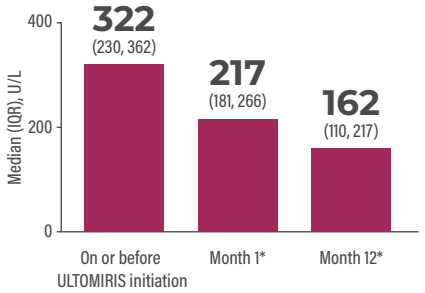
Physician and patient demographics: a total of 25 physicians provided charts for 36 adult patients with atypical-HUS in the study. Of those patients, 2 (5.6%) had a kidney transplantation prior to eculizumab treatment and 3 (8.3%) had prior dialysis (within 12 months and up to 2 weeks after starting ULTOMIRIS). The mean age (SD) at index date was 44 years (16).

A physician panel–based chart review study: clinical outcomes

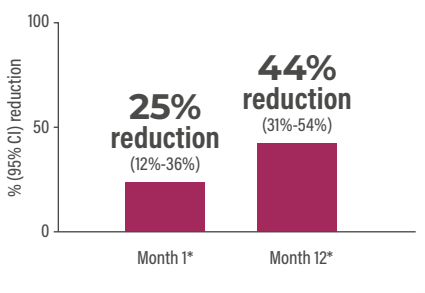
Median (IQR) platelet count



Median (IQR) LDH levels



Reduction of mean (95% CI) SCr levels



Complete TMA response was achieved in 26 patients (72.2%) within 18 months of eculizumab initiation and early switch to ULTOMIRIS

Note: Data are from an abstract. **Limitations to the study were not disclosed.**
*Following ULTOMIRIS initiation.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Most common adverse reactions in patients with aHUS (incidence ≥20%) were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension and pyrexia. Serious adverse reactions were reported in 42 (57%) patients with aHUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia and abdominal pain.

Adverse reactions reported in ≥20% of pediatric patients treated with ULTOMIRIS were diarrhea, constipation, vomiting, pyrexia, upper respiratory tract infection, decreased vitamin D, headache, cough, rash, and hypertension.

Adult patients with atypical-HUS preferred ULTOMIRIS®4*

In a web-based survey of adult US patients (N=50) with confirmed atypical-HUS who had previously received therapy with eculizumab and ≥3 doses of ULTOMIRIS

Adult patient-reported survey: proportion of patients (%) who preferred ULTOMIRIS vs preferring eculizumab or having no preference

Frequency of infusions	Travel/vacation	Benefit to quality of life	Planning social activities	Length of time to receive infusion
100%	98%	86%	86%	74%
n/N=50/50	n/N=48/49	n/N=43/50	n/N=42/49	n/N=37/50

Adult patients were asked about how ULTOMIRIS impacted them based on their experience during their treatment with eculizumab and after switching to ULTOMIRIS†

While receiving treatments, I was able to enjoy life	The frequency of infusions did not disrupt my life	The frequency of infusions did not impact my ability to go to work/school
92%	96%	94%
n/N=45/49	n/N=48/50	n/N=33/35

For the same questions, results seen with eculizumab were 66% (n/N=33/50), 28% (n/N=14/50), and 40% (n/N=14/35), respectively.

For patients who responded "not applicable," responses were excluded from the percentage calculation for each question. Mean durations of eculizumab and ULTOMIRIS treatment were 46.9 and 12.9 months, respectively.

*Survey included adult patients and caregivers of pediatric patients; only adult patient data presented. The participant sample consisted predominantly of White and non-Hispanic/Latino individuals, females, and those educated to a college level or higher, limiting the generalizability of the findings to the wider population. There was potential for recall bias given that the participants had more recent experience with ULTOMIRIS than eculizumab.

†Percentages represent the percent of patients who agreed "quite a bit/very much" with the survey question or agreed "not at all/a little bit" to the inverse of the question presented here.

HUS=hemolytic uremic syndrome.

Please see additional Important Safety Information throughout and the accompanying Patient Information and Instructions for Use in the full Prescribing Information (UltomirisHCP.com/PI) for ULTOMIRIS (ravulizumab), including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, or scan the QR code on Page 1.

SELECT IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

Plasma Exchange, Plasmapheresis, and Intravenous Immunoglobulins

Concomitant use of ULTOMIRIS with plasma exchange (PE), plasmapheresis (PP), or intravenous immunoglobulin (IVIg) treatment can reduce serum ravulizumab concentrations and requires a supplemental dose of ULTOMIRIS.

Neonatal Fc Receptor Blockers

Concomitant use of ULTOMIRIS with neonatal Fc receptor (FcRn) blockers (e.g., efgartigimod) may lower systemic exposures and reduce effectiveness of ULTOMIRIS. Closely monitor for reduced effectiveness of ULTOMIRIS.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

Considerations for starting ULTOMIRIS

Because of the risk of serious meningococcal infections, **ULTOMIRIS** is available only through a restricted program under a **Risk Evaluation and Mitigation Strategy** (REMS) called **ULTOMIRIS** and **SOLIRIS REMS**.[1]

Enrollment in REMS is mandatory[1]

https://ultsolrems.com/#Main/HealthCareProvider

Vaccination against meningococcal infection should be at least 2 weeks prior to administering the first dose of a C5 inhibitor in accordance with ACIP recommendations. If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible.[1]

OneSource™ is a complimentary, personalized patient support program available for patients, families, and caregivers facing complement-mediated diseases to help them start and stay on the treatment as prescribed.

Consider enrolling your patient into OneSource (optional)

https://alexiononesource.com

For eligible patients, OneSource can help with various challenges such as vaccination, benefits investigation, prior authorization, financial assistance, and much more.

ONESOURCE®
Personalized Patient Support from Alexion

Some considerations for prior authorization, subject to variability depending on scenario and health insurance

Naïve start on ULTOMIRIS

Diagnosis of atypical-HUS[1,11]:
ADAMTS13 test results, negative Shiga toxin

Vaccination verification[1]:
proof of meningococcal vaccination

Switch to ULTOMIRIS

Diagnosis of atypical-HUS[1,11]:
ADAMTS13 test results, negative Shiga toxin

Vaccination verification[1]:
proof of meningococcal vaccination

Demonstrated improvement with C5 inhibition:
consider highlighting hematologic and renal parameters associated with atypical-HUS

Statement of previous C5 inhibitor discontinuation prior to ULTOMIRIS initiation

Need help
or have questions about starting your patient on ULTOMIRIS?
Contact your representative

ACIP=Advisory Committee on Immunization Practices; ADAMTS13=a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13; C5=complement component 5; HUS=hemolytic uremic syndrome.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial


Actor portrayal

Why wait?

Start or switch your adult patients to ULTOMIRIS® today!

Have questions?
Talk to your atypical-HUS representative

HUS=hemolytic uremic syndrome.

SELECT IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy. Healthcare providers and patients may call 1-833-793-0563 or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and the accompanying Patient Information and Instructions for Use in the full Prescribing Information (UltomirisHCP.com/PI) for ULTOMIRIS (ravulizumab), including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, or scan the QR code on Page 1.

References: 1. ULTOMIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. **2**. Data on file. Alexion Pharmaceuticals, Inc. **3**. Rondeau E, et al. *Kidney Int*. 2020;97(6):1287-1296. **4**. Mauch TJ, et al. *J Comp Eff Res*. 2023;12(9):e230036. **5**. Dixon BP, et al. *Kidney Med*. 2024;6(8):100855. **6**. Dixon BP, et al. *Kidney Med*. 2024;6(8):100855. [supplementary]. **7**. Padilla O, Abadie J. Blood tests: normal values. Merck Manual Professional Version. **8**. Chen TK, et al. *JAMA*. 2019;322(13):1294-1304. **9**. KDIGO CKD Work Group. *Kidney Int*. 2024;105(4S):S117-S314. **10**. Chaturvedi S, et al. Abstract presented at: American Society of Hematology Annual Meeting; December 7-10, 2024; San Diego, California. **11**. Laurence J, et al. *Clin Adv Hematol Oncol*. 2016;14(11)(suppl 11):2-15.

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AstraZeneca Rare Disease