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

CODING AND BILLING GUIDE FOR THE USE OF ULTOMIRIS

In Adult Patients With Neuromyelitis Optica Spectrum Disorder (NMOSD) Who Are Anti-Aquaporin 4 (AQP4) Antibody-Positive[1]

INDICATION

ULTOMIRIS is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.

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)*].

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Purpose of This Guide

Alexion Pharmaceuticals, Inc. has developed the ULTOMIRIS® (ravulizumab-cwvz) Coding and Billing Guide to provide objective and publicly available coding and billing information.

This document is provided for informational purposes only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payer. Alexion does not warrant, promise, guarantee, or make any statement that the use of this information will result in coverage or payment for ULTOMIRIS or that any payment received will cover providers' costs. Alexion is not responsible for any action providers take in billing for, or appealing, ULTOMIRIS claims.

Hospitals and physicians are responsible for compliance with Medicare and other payer rules and requirements and for the information submitted with all claims and appeals. Before any claims or appeals are submitted, hospitals and physicians should review official payer instructions and requirements, should confirm the accuracy of their coding or billing practices with these payers, and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.

Please visit **www.ULTOMIRIS.com** for additional information, or call 1-888-765-4747 to speak with the Alexion OneSource™ Team.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Coding for ULTOMIRIS® (ravulizumab-cwvz) in Adult Patients with Neuromyelitis Optica Spectrum Disorder (NMOSD) Who Are Anti-Aquaporin 4 (AQP4) Antibody-Positive

Diagnosis Coding

The following *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes may be appropriate to describe adult patients diagnosed with NMOSD who are anti-AQP4 antibody-positive:

ICD-10-CM Diagnosis Code[1]	Code Descriptor
G36.0	Neuromyelitis optica [Devic]

Drug Coding

The following drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code can be reported on medical claim forms to payers:

HCPCS Code[2,a]	Code Descriptor
J1303	Injection, ravulizumab-cwvz, 10 mg

Beginning January 1, 2023, the following HCPCS modifiers may be required for ULTOMIRIS, as applicable:

Modifier[2]	Description	Commercial Requirement	Medicare Requirement
JZ[b]	Zero drug amount discarded/not administered to any patient	Varies by payer	Y
JG[c]	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	N	Y
RE	Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)	Y	Y
TB[c]	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	N	Y

IMPORTANT NOTE: CMS will start auditing claims for "JZ" modifiers on July 1, 2023. CMS will start **rejecting claims** without "JW" or "JZ" modifiers on October 1, 2023. "JG" and "TB" are required on Medicare claims no later than January 1, 2024.

Note: other modifiers may apply to HCPCS coding.

a. Applies to all available ULTOMIRIS vials/National Drug Codes (NDCs). **b.** Modifier "JZ" is effective for claims with dates of service (DOS) on and after January 1, 2023. CMS will start auditing claims for "JZ" modifiers on claims with single/multisource single-dose packaged drugs on outpatient claims starting DOS July 1, 2023, and start rejecting claims without these modifiers effective October 1, 2023.[3] **c.** 340B entities paid under the Medicare Outpatient Prospective Payment System (OPPS) are required to report either modifier "JG" or "TB" on OPPS claims beginning January 1, 2023. No later than January 1, 2024, 340B modifiers, "JG" or "TB" are required on Medicare claims for separately payable Part B-covered drugs and biologicals that are acquired through the discount program for all 340B-covered entities, including hospital-based and nonhospital-based entities.[4]

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Coding for ULTOMIRIS® (ravulizumab-cwvz) in Adult Patients with NMOSD Who Are Anti-AQP4 Antibody-Positive (cont.)

Some payers, including Medicaid, require drugs like ULTOMIRIS to be billed on medical claims with the product's National Drug Code (NDC) in addition to the HCPCS code. Payers typically require healthcare professionals to use the Health Insurance Portability and Accountability Act (HIPAA)-compliant, 11-digit NDC format[5]:

11-Digit NDC[5,6]	Code Descriptor	Strength
25682-0025-01	ULTOMIRIS for intravenous use, single-dose vial	300 mg/3 mL
25682-0028-01	ULTOMIRIS for intravenous use, single-dose vial	1100 mg/11 mL

Please note that payers have different guidance for placement of the NDC on medical claims. Typically, the 11-digit NDC is reported without any dashes or other punctuation.[4]

Some payers may also require a unit of measure (UoM) qualifier. For ULTOMIRIS, the unit of measure qualifier is mL (milliliter).

Check payer requirements for reporting the NDC and UoM on claims.

Drug Administration Services

Payers may offer separate coverage and reimbursement for drug administration services. The following are possible ICD, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes to report the administration of ULTOMIRIS in inpatient settings:

ICD-10-PCS[7]	Code Descriptor
3E033GR	Introduction of other therapeutic monoclonal antibody into peripheral vein, percutaneous approach
3E043GR	Introduction of other therapeutic monoclonal antibody into central vein, percutaneous approach

The following Current Procedural Terminology (CPT®) codes may be appropriate to report administration of ULTOMIRIS in physician offices and hospital outpatient facilities. Individual payer policies should be reviewed for reporting requirements.

CPT Code[8]	Code Descriptor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one hour
+ 96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to primary procedure)
96413[a]	Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance/drug
+ 96415[a]	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to primary procedure)

a. Billing highly complex administration codes (96413 and 96415) requires the provider in the medical record to document the complexity beyond what is required for therapeutic infusions (96365 and 96366).[7]

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Coding for Meningococcal Vaccination

Diagnosis Coding

For an encounter strictly for the vaccination, the diagnosis code for prophylactic vaccination is assigned along with the diagnosis code for NMOSD and any other conditions the patient may have.

ICD-10-CM Diagnosis Code[1]	Code Descriptor
Z23	Encounter for immunization

Vaccine Coding

Coverage of meningococcal vaccines may vary by payer. Prescribers should consult respective payer billing guidelines.

CPT Code[8]	Code Descriptor
90619	Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, tetanus toxoid carrier (MenACWY-TT), for intramuscular use
90620	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B (MenB-4C), 2-dose schedule, for intramuscular use
90621	Meningococcal recombinant lipoprotein vaccine, serogroup B (MenB-FHbp), 2- or 3-dose schedule, for intramuscular use
90733	Meningococcal polysaccharide vaccine, serogroups A, C, Y, W-135, quadrivalent (MPSV4), for subcutaneous use
90734	Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, diphtheria toxoid carrier (MenACWY-D) or CRM197 carrier (MenACWY-CRM), for intramuscular use

Vaccine Administration Coding

The following CPT codes may be appropriate to report administration of meningococcal vaccines in outpatient settings.

CPT Code[8]	Code Descriptor
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
+ 90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Claim Forms

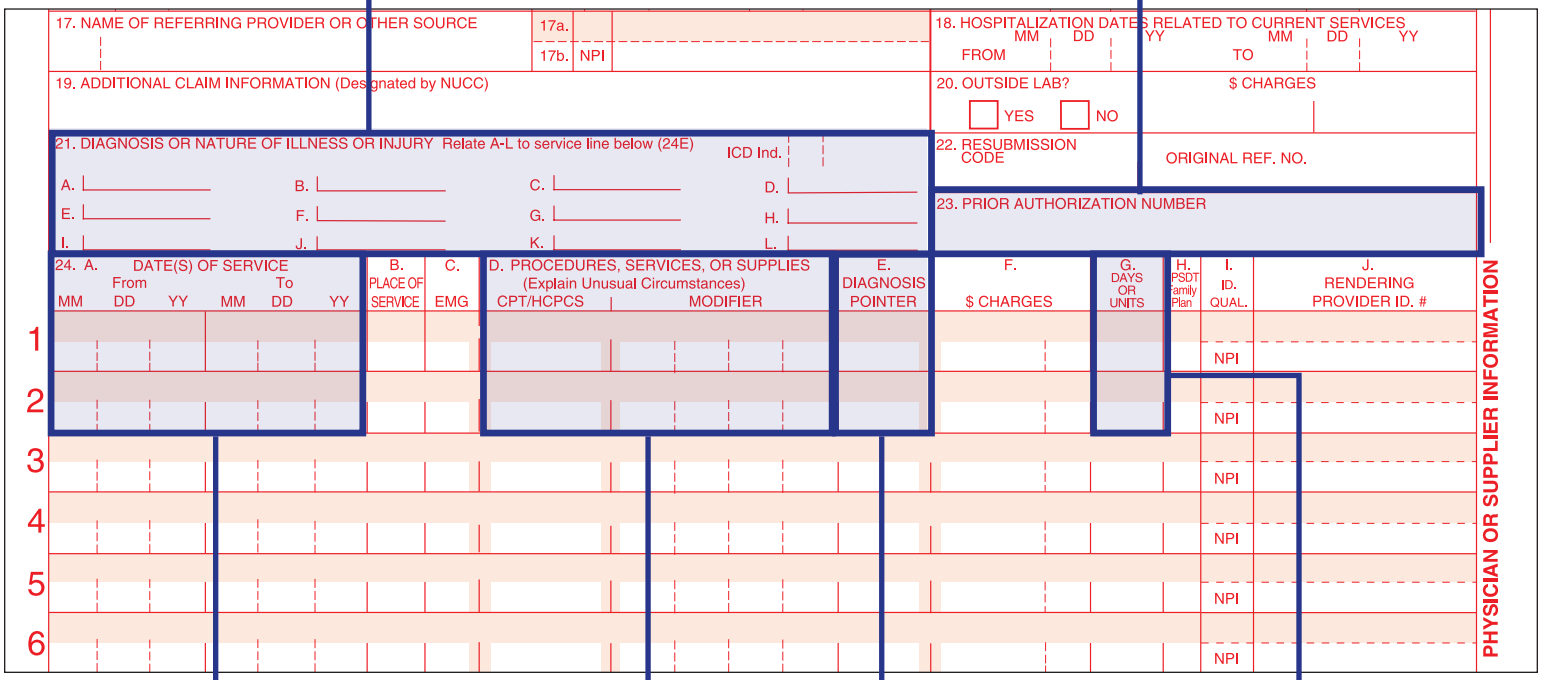
Sample CMS-1500 (or the electronic equivalent 837P): Physician Office[9]

For an example of a completed CMS-1500 form, go to page 7.

Item 21 Diagnosis: Enter the appropriate diagnosis code, eg,
- ICD-10-CM **G36.0** for neuromyelitis optica [Devic]

Note: Other diagnosis codes may apply.

Item 23 Prior Authorization: Enter the prior authorization number assigned by the payer.



Item 24A Date(s) of Service: Enter the NDC number in the shaded area and the month, day, and year in the white space below.

Note: Check payer requirements and format for reporting NDC.

Item 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1303** for ULTOMIRIS® (ravulizumab-cwvz) per 10 mg
- Applicable modifiers:
  - **JZ** Zero drug amount discarded/not administered to any patient
  - **RE** Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21.

Item 24G Units: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1500 (or the electronic equivalent 837P): Physician Office[9]

Example claim form for an ULTOMIRIS® (ravulizumab-cwvz) IV infusion:

To achieve an ULTOMIRIS loading dose of 3000 mg for a patient ≥100 kg, the following vial combination was used:

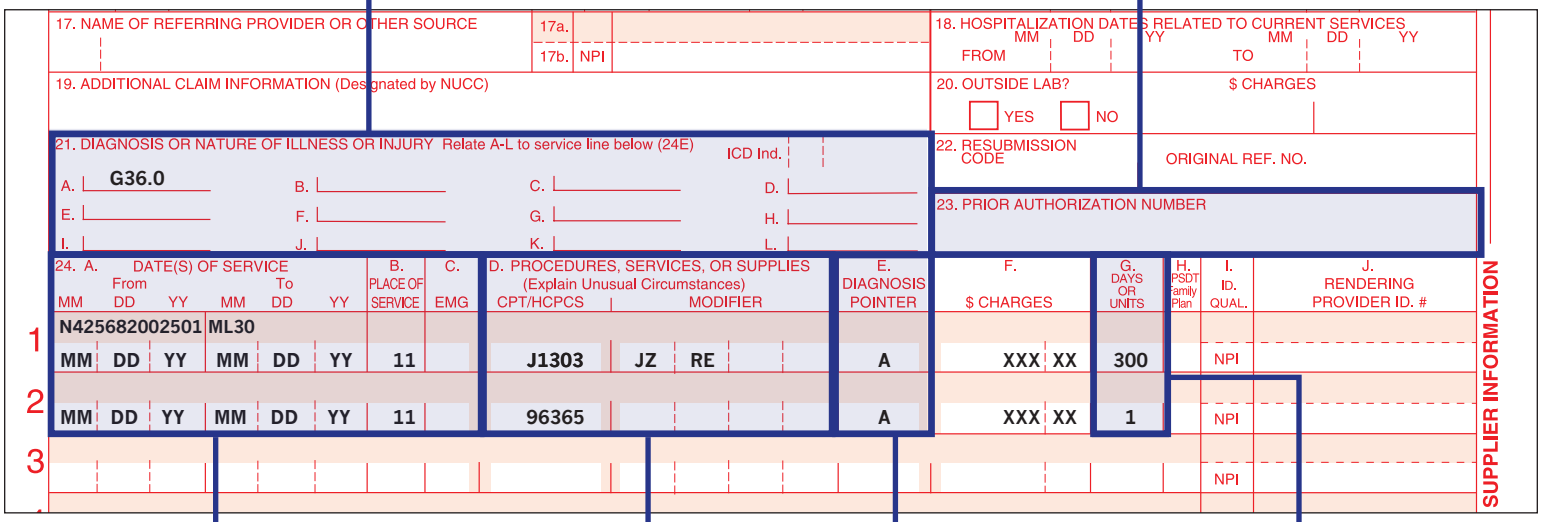
- 10 single-dose 300 mg/3 mL vials (NDC 25682-0025-01)

Item 21 Diagnosis: Enter the appropriate diagnosis code, eg,

- ICD-10-CM **G36.0** for neuromyelitis optica [Devic]

Note: Other diagnosis codes may apply.

Item 23 Prior Authorization: Enter the prior authorization number assigned by the payer.



Item 24A Date(s) of Service: Enter the NDC number in the shaded area and the month, day, and year in the white space below. The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may also require a Unit of Measure (UoM); eg,

- N4256820002501 ML30

Note: Check payer requirements and format for reporting NDC.

Item 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- Drug: **J1303** for ULTOMIRIS® (ravulizumab-cwvz) per 10 mg
- Applicable modifiers:
  - **JZ** Zero drug amount discarded/not administered to any patient
  - **RE** Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21.

Item 24G Units: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

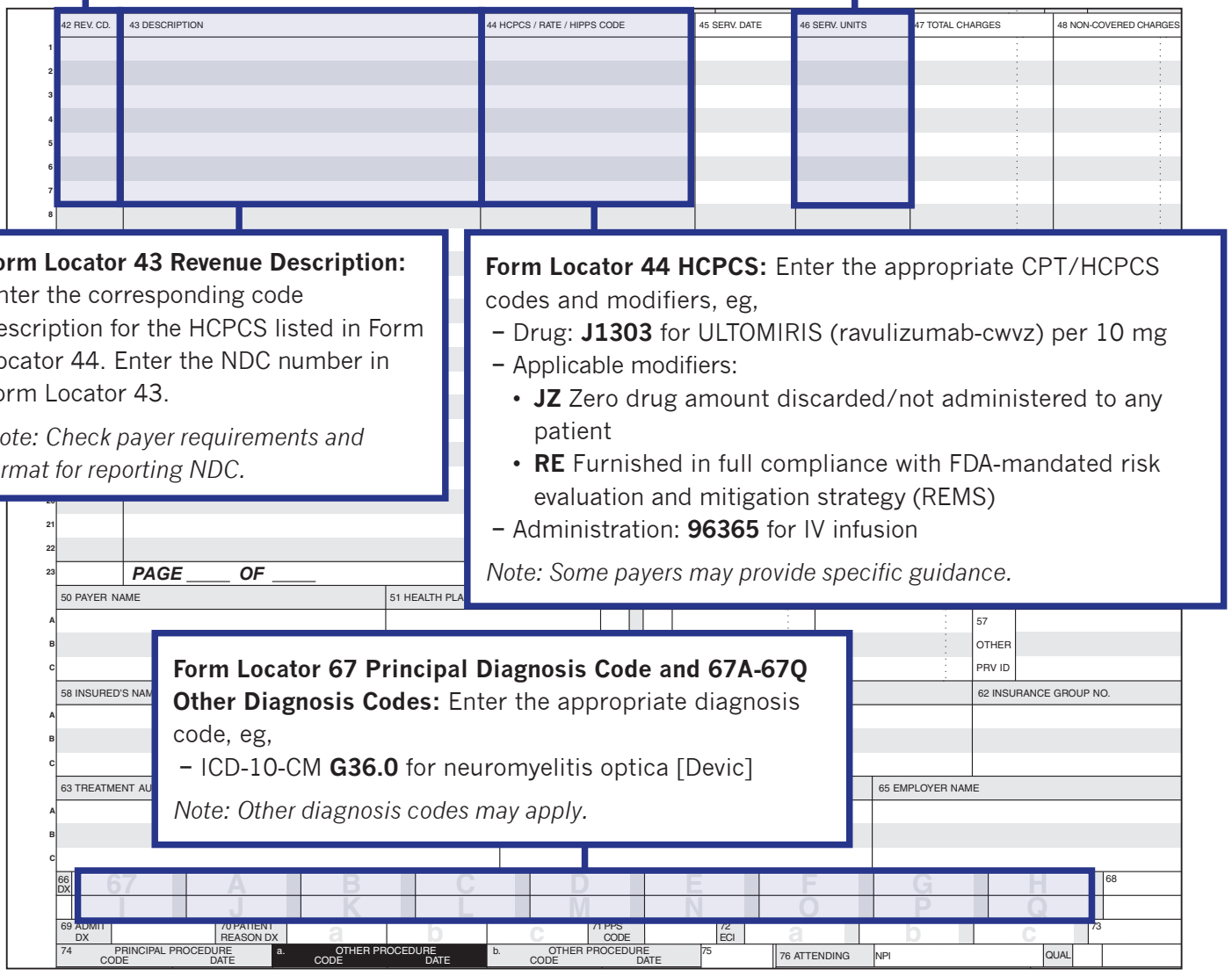
Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility[10]

For an example of a completed CMS-1450 form, go to page 9.

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,
- **0636** for ULTOMIRIS® (ravulizumab-cwvz)
- **0260** for IV infusion

Note: Other revenue codes may apply.

Form Locator 46 Units of Service: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.



Form Locator 43 Revenue Description: Enter the corresponding code description for the HCPCS listed in Form Locator 44. Enter the NDC number in Form Locator 43.

Note: Check payer requirements and format for reporting NDC.

Form Locator 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1303** for ULTOMIRIS (ravulizumab-cwvz) per 10 mg
- Applicable modifiers:
  - **JZ** Zero drug amount discarded/not administered to any patient
  - **RE** Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Form Locator 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code, eg,
- ICD-10-CM **G36.0** for neuromyelitis optica [Devic]

Note: Other diagnosis codes may apply.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility[10]

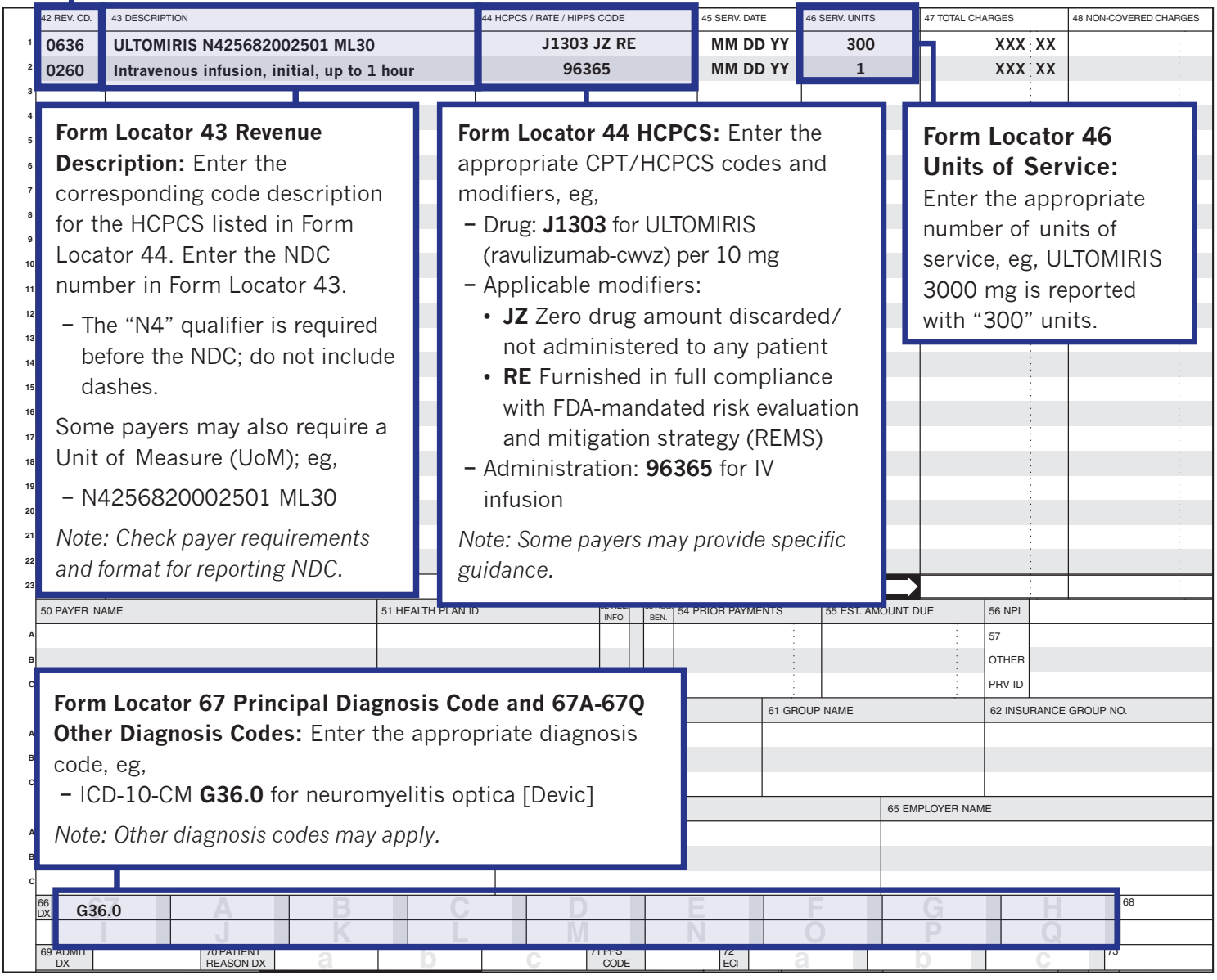
Example claim form for an ULTOMIRIS® (ravulizumab-cwvz) IV infusion:

To achieve an ULTOMIRIS loading dose of 3000 mg for a patient ≥100 kg, the following vial combination was used:

- 10 single-dose 300 mg/3 mL vials (NDC 25682-0025-01)

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,
- **0636** for ULTOMIRIS
- **0260** for IV infusion

Note: Other revenue codes may apply.



Form Locator 43 Revenue Description: Enter the corresponding code description for the HCPCS listed in Form Locator 44. Enter the NDC number in Form Locator 43.
- The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may also require a Unit of Measure (UoM); eg,
- N4256820002501 ML30

Note: Check payer requirements and format for reporting NDC.

Form Locator 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1303** for ULTOMIRIS (ravulizumab-cwvz) per 10 mg
- Applicable modifiers:
  - **JZ** Zero drug amount discarded/ not administered to any patient
  - **RE** Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Form Locator 46 Units of Service: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.

Form Locator 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code, eg,
- ICD-10-CM **G36.0** for neuromyelitis optica [Devic]

Note: Other diagnosis codes may apply.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Explore Alexion Access Navigator

ALEXION ACCESS NAVIGATOR

Alexion Access Navigator is a dedicated resource website for US Healthcare Professionals and their offices that contains downloadable access and reimbursement materials for ULTOMIRIS® (ravulizumab-cwvz).

Online: https://alexionaccessnavigator.com

OneSource™ Offers Patient Support

Contact OneSource™:

Phone:	**Online:**
1-888-765-4747	https://alexiononesource.com

SELECT IMPORTANT SAFETY INFORMATION (cont.)

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

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.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

SELECT IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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.

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*. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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
Intravenous administration 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 treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

ADVERSE REACTIONS

Most common adverse reactions in adult patients with NMOSD (incidence >10%) were COVID-19, headache, back pain, arthralgia, and urinary tract infection. Serious adverse reactions were reported in 8 (13.8%) patients with NMOSD receiving ULTOMIRIS.

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.

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 accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Please see Important Safety Information on pages 1 and 10-11 and accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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ALEXION® AstraZeneca Rare Disease