CODING AND BILLING GUIDE FOR THE USE OF SOLIRIS® (eculizumab)

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

INDICATION

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

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

SOLIRIS, 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 SOLIRIS, unless the risks of delaying SOLIRIS 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 SOLIRIS 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, SOLIRIS 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 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

SOLIRIS®
(eculizumab)
Injection for Intravenous Use
300 mg/30 mL vial

US/SOL-N/0057 V4 04/2024

Purpose of This Guide

Alexion Pharmaceuticals, Inc. has developed the SOLIRIS® (eculizumab) 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 SOLIRIS, or that any payment received will cover providers' costs. Alexion is not responsible for any action providers take in billing for, or appealing, SOLIRIS 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 https://SOLIRISnmosd-hcp.com/support-and-resources/resources 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 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Coding for SOLIRIS® (eculizumab) in anti-AQP4 antibody-positive NMOSD

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 anti-AQP4 antibody-positive NMOSD:

ICD-10-CM Diagnosis Code[2]	Code Descriptor
G36.0	Neuromyelitis optica [Devic]

The ICD-10-CM diagnosis codes above may map to the following Medicare Severity-Diagnosis Related Groups (MS-DRGs):

MS-DRG[3]	Code Descriptor
058	Multiple Sclerosis and Cerebellar Ataxia with MCC
059	Multiple Sclerosis and Cerebellar Ataxia with CC
060	Multiple Sclerosis and Cerebellar Ataxia without CC/MCC

Key: CC – complication or comorbidity; MCC – major complication or comorbidity.

Drug Coding

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

HCPCS Code[4]	Code Descriptor
J1300	Injection, eculizumab, 10 mg

The following HCPCS modifiers may be required for SOLIRIS, as applicable:

Modifier[4]	Description	Commercial Requirement	Medicare Requirement
JZ	Zero drug amount discarded/not administered to any patient	Varies by payer	Y
JG	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	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	N	Y

Some payers, including Medicaid, require drugs such as SOLIRIS 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]:

NDC[1]	Code Descriptor
11-Digit	25682-0001-01 SOLIRIS (eculizumab single-use vial, 300 mg/30 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.

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

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

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Coding for SOLIRIS® (eculizumab) in anti-AQP4 antibody-positive NMOSD (cont.)

Drug Administration Services

The following Current Procedural Terminology (CPT®) codes may be appropriate to report administration of SOLIRIS in a physician's office or outpatient hospital facilities:

CPT[6]	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]

ICD-10-PCS Codes for Inpatient Only

The following International Classification Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes may be appropriate to report the administration of Soliris in acute inpatient hospitals:

Code[8]	Code Descriptor
XW033C6	Introduction of eculizumab into *peripheral vein*, percutaneous approach, new technology group
XW043C6	Introduction of eculizumab into *central vein*, percutaneous approach, new technology group

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, 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[2]	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[6]	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
90749	Unlisted vaccine/toxoid

Vaccine Administration Coding

CPT Code[6]	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 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Claim Forms

Sample CMS-1500: Physician Office

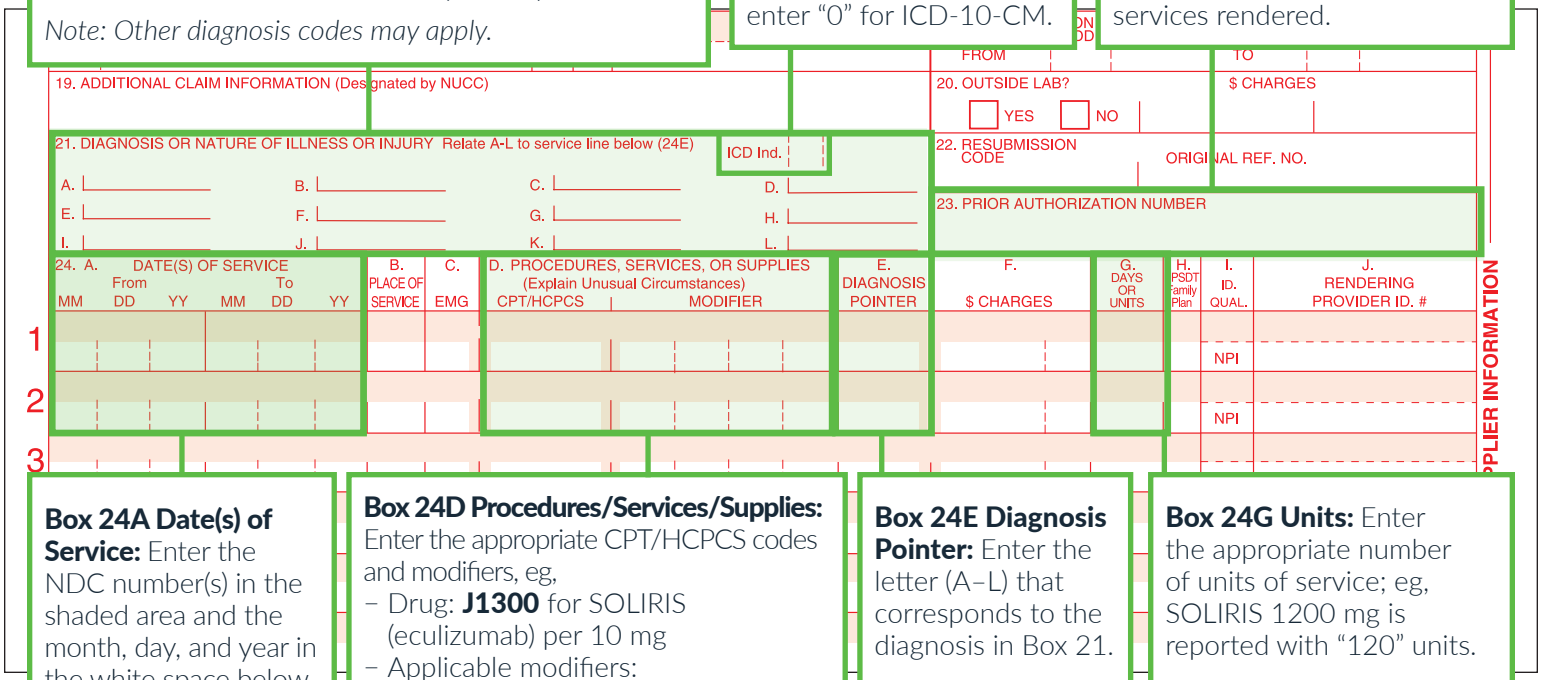
For an example of a completed CMS-1500 form, go to page 7.

Box 21 Diagnosis: Enter the appropriate diagnosis code; eg,
- ICD-10-CM G36.0 for Neuromyelitis optica [Devic]

Note: Other diagnosis codes may apply.

Box 21 ICD Indicator: Identify the type of ICD diagnosis code used; eg, enter "0" for ICD-10-CM.

Box 23 Prior Authorization: Enter the prior authorization number as obtained prior to services rendered.



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

Box 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1300** for SOLIRIS (eculizumab) 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: **96xxx**

Note: Some payers may provide specific guidance.

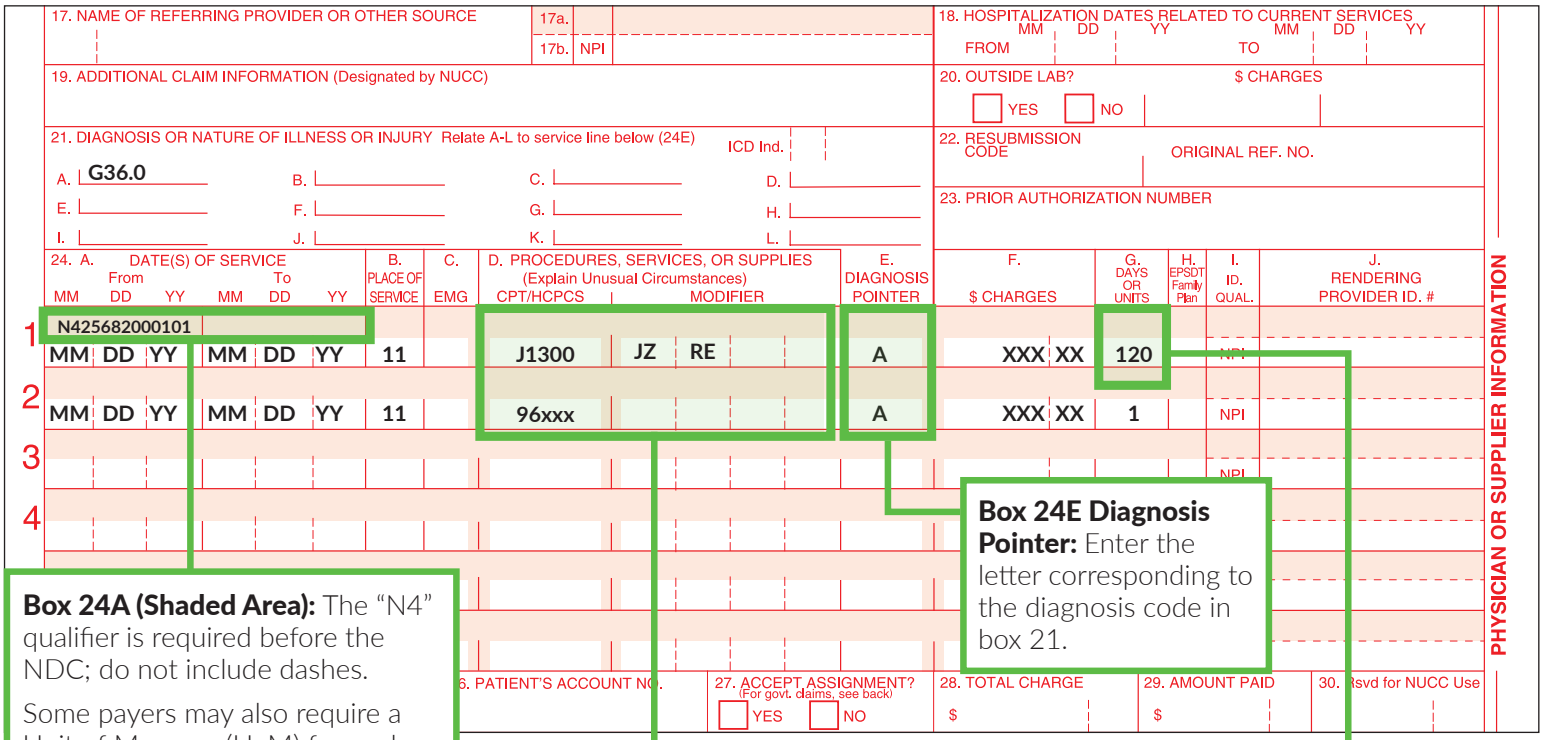
Box 24E Diagnosis Pointer: Enter the letter (A–L) that corresponds to the diagnosis in Box 21.

Box 24G Units: Enter the appropriate number of units of service; eg, SOLIRIS 1200 mg is reported with "120" units.

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1500: Physician Office

Example claim form for a SOLIRIS® (eculizumab) maintenance dose of 1200 mg IV infusion:



Box 24A (Shaded Area): The "N4" qualifier is required before the NDC; do not include dashes.

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

- N425682000101 ML120

Note: Double check payer requirements and format for reporting the UoM.

Box 24E Diagnosis Pointer: Enter the letter corresponding to the diagnosis code in box 21.

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

- Drug: **J1300** for SOLIRIS (eculizumab) 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: **96xxx**

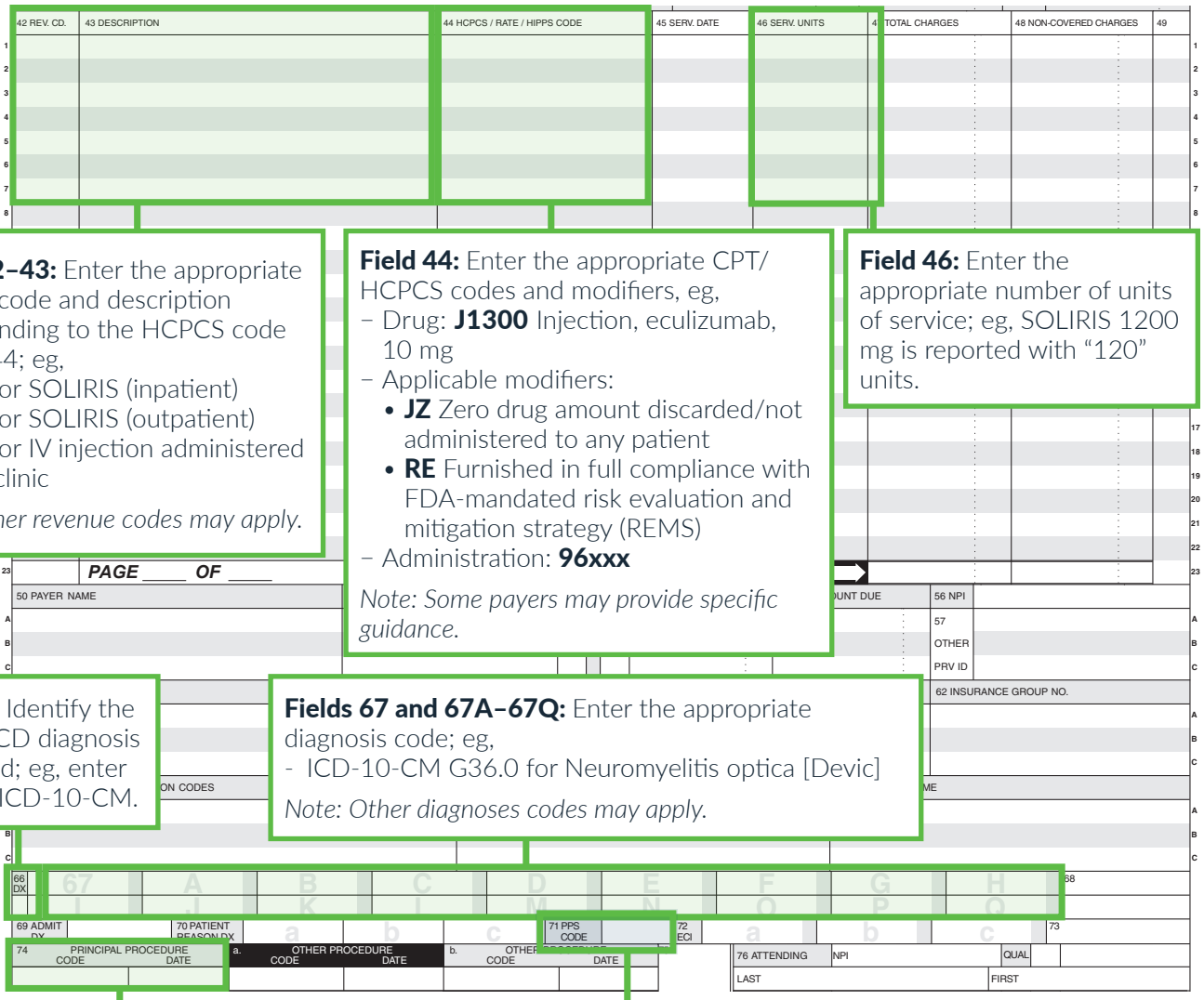
Note: Some payers may provide specific guidance.

Box 24G Days or Units: Applying the 10 mg billing unit for J1300 to the total administered dose of 1200 mg results in 120 billing units.

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1450: Hospital

For an example of a completed CMS-1450 form, go to pages 9 and 10.



Fields 42–43: Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44; eg,
- 0250 for SOLIRIS (inpatient)
- 0636 for SOLIRIS (outpatient)
- 0510 for IV injection administered in the clinic

Note: Other revenue codes may apply.

Field 44: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1300** Injection, eculizumab, 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: **96xxx**

Note: Some payers may provide specific guidance.

Field 46: Enter the appropriate number of units of service; eg, SOLIRIS 1200 mg is reported with "120" units.

Field 66: Identify the type of ICD diagnosis code used; eg, enter a "0" for ICD-10-CM.

Fields 67 and 67A–67Q: Enter the appropriate diagnosis code; eg,
- ICD-10-CM G36.0 for Neuromyelitis optica [Devic]

Note: Other diagnoses codes may apply.

Field 74: Enter principal ICD-10-PCS code; eg,
- XW033C6 for peripheral vein administration
- XW043C6 for central vein administration

Field 71: Enter the appropriate DRG code.

Note this field is not required for Medicare.

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1450: Hospital Outpatient

Example claim form for a SOLIRIS® (eculizumab) maintenance dose of 1200 mg IV infusion:

HOSPITAL OUTPATIENT

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
1		N425682000101					
2	0636	Drug requiring detailed coding (SOLIRIS)	J1300 JZ RE	MM DD YY	120	XXX XX	
3	0510	Clinic, general (Injection)	96xxx	MM DD YY	1	XXX XX	
4							
17							
18							
19							
20							
21							
22							
23		PAGE _____ OF _____	CREATION DATE		TOTALS		

Field 43 Description: The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may require a Unit of Measure (UoM) for each NDC; eg,
– N425682000101 ML120

Note: Double check payer requirements and format for reporting the UoM.

Field 44: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
– Drug: **J1300** Injection, eculizumab, 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: **96xxx**

Note: Some payers may provide specific guidance.

Field 46: Applying the 10 mg billing unit for J1300 to the total administered dose of 1200 mg results in 120 billing units.

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
A							57 OTHER PRV ID
B							
C							

	58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A					
B					
C					

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A			
B			
C			

66 DX | 67 | A | B | C | D | E | F | G | H | 68
I | J | K | L | M | N | O | P | Q

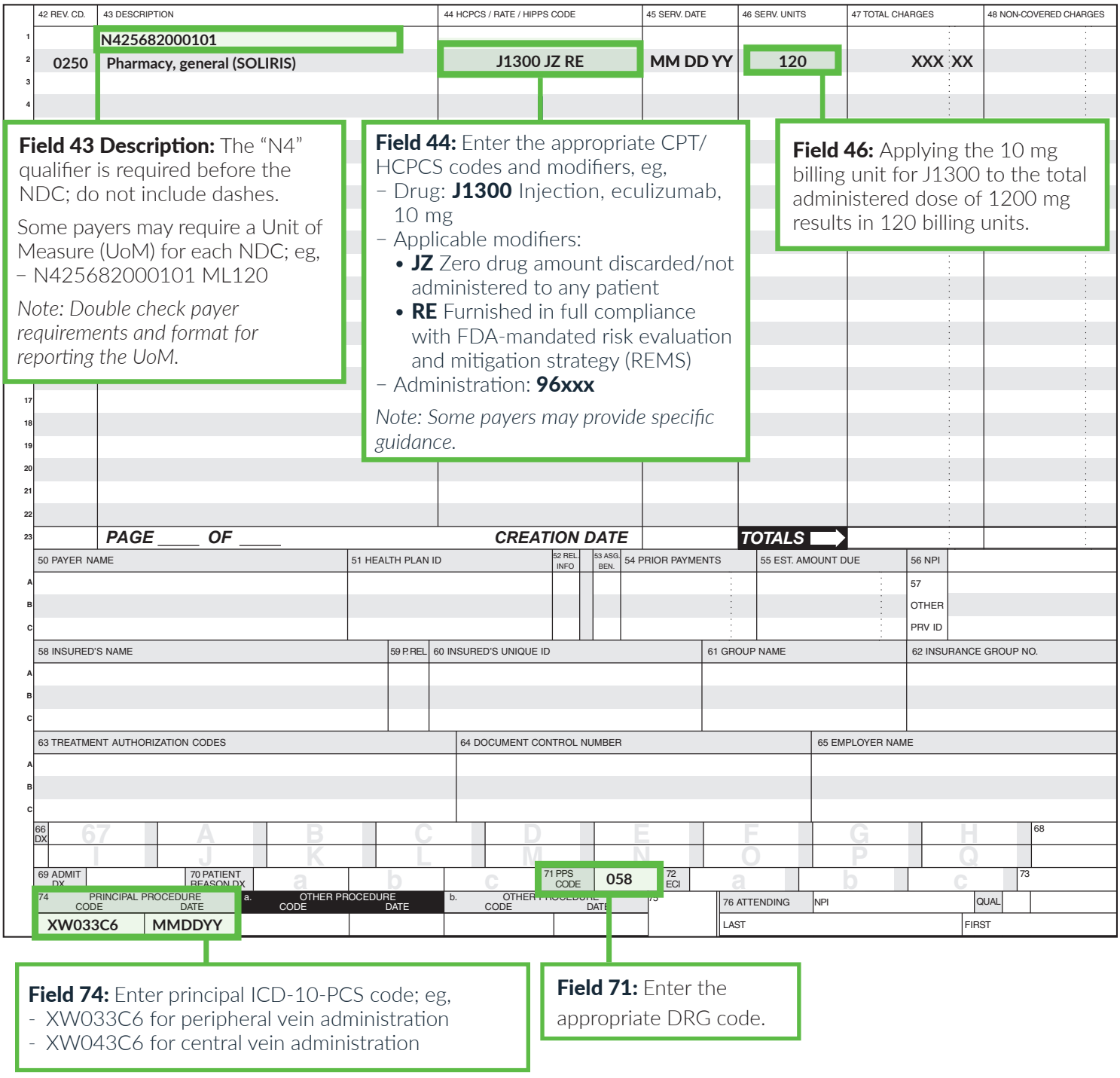
69 ADMIT DX | 70 PATIENT REASON DX | a | b | c | 71 PPS CODE | 72 ECI | a | b | c | 73

74 PRINCIPAL PROCEDURE CODE DATE | a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75 | 76 ATTENDING NPI QUAL | LAST FIRST

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Sample CMS-1450: Hospital Inpatient

Example claim form for a SOLIRIS® (eculizumab) maintenance dose of 1200 mg IV infusion:



Field 43 Description: The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may require a Unit of Measure (UoM) for each NDC; eg,
– N425682000101 ML120

Note: Double check payer requirements and format for reporting the UoM.

Field 44: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
– Drug: **J1300** Injection, eculizumab, 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: **96xxx**

Note: Some payers may provide specific guidance.

Field 46: Applying the 10 mg billing unit for J1300 to the total administered dose of 1200 mg results in 120 billing units.

Field 74: Enter principal ICD-10-PCS code; eg,
- XW033C6 for peripheral vein administration
- XW043C6 for central vein administration

Field 71: Enter the appropriate DRG code.

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, 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 SOLIRIS® (eculizumab).

Online: https://alexionaccessnavigator.com

OneSource™ Offers Patient Support

Contact OneSource:

Phone:
1-888-765-4747

Online:
https://alexiononesource.com

SELECT IMPORTANT SAFETY INFORMATION (cont.)

CONTRAINDICATIONS

- SOLIRIS is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

SOLIRIS, 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 therapy with SOLIRIS. 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 SOLIRIS 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 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 SOLIRIS. The benefits and risks of treatment with SOLIRIS, 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 these signs and symptoms occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of SOLIRIS in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, SOLIRIS 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 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 SOLIRIS. 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 SOLIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, the signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card with them at all times during and for 3 months following SOLIRIS treatment.

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

Please see Important Safety Information on pages 1 and 11-12 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

SELECT IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Other Infections

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

SOLIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Patients receiving SOLIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during SOLIRIS treatment has not been established. Therefore, treatment with SOLIRIS should not alter anticoagulant management.

Infusion-Related Reactions

Administration of SOLIRIS may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which required discontinuation of SOLIRIS. Interrupt SOLIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

ADVERSE REACTIONS

The most frequently reported adverse reactions in the NMOSD placebo-controlled trial (≥10%) were: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

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 SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

References

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