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

In Paroxysmal Nocturnal Hemoglobinuria (PNH)

INDICATION

Paroxysmal Nocturnal Hemoglobinuria (PNH)
Soliris is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.[1]

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

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

US/SOL-P/0029 04/22

Product Overview[1]

SOLIRIS® (eculizumab) is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

SOLIRIS is administered as an intravenous (IV) infusion (not as an IV push or bolus injection), lasting about 35 minutes in adults.

SOLIRIS is supplied as a 300 mg /30 mL (10 mg/mL) single-dose vial.

Infusions for PNH usually occur in a physician office, infusion center, hospital outpatient clinic, or patient home.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris and may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risk of developing a meningococcal infection. (See *Serious Meningococcal Infections* for additional guidance on the management of the risk of meningococcal infection).**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at www.solirisrems.com.

Contraindications

- Patients with unresolved serious *Neisseria meningitidis* infection
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection

Warnings and Precautions

Serious Meningococcal Infections

Risk and Prevention

The use of Soliris increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis).

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If Soliris must be initiated immediately in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide 2 weeks of antibacterial drug prophylaxis. Discontinue Soliris in patients who are undergoing treatment for serious meningococcal infections.

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions (cont.)

Serious Meningococcal Infections (cont.)

REMS

Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s).

Other Infections

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

Patients may have increased susceptibility to infections, especially with encapsulated bacteria. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Use caution when administering Soliris to patients with any systemic infection.

Monitoring Disease Manifestations After Soliris Discontinuation

Treatment Discontinuation for PNH

Monitor patients after discontinuing Soliris for at least 8 weeks to detect hemolysis.

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. 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 PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea.

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

Purpose of This Guide and Disclaimer

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 www.SOLIRIS.net for additional information or for inquiries regarding reimbursement, please call 1-888-765-4747 to speak with a OneSource™ patient support specialist who can connect you with your local Field Reimbursement Manager (FRM). OneSource™ is available Monday through Friday, 8:30 AM–8 PM EST.

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

Coding for SOLIRIS® (eculizumab) in PNH

Diagnosis Coding

The following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis code may be appropriate to describe patients diagnosed with PNH:

ICD-10-CM Diagnosis Code[2]	Code Descriptor
D59.5	Paroxysmal nocturnal hemoglobinuria

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[3]	Code Descriptor
J1300	Injection, eculizumab, 10 mg

Some payers may also require the use of HCPCS modifier -RE to indicate SOLIRIS was administered in full compliance with the REMS program.

Some payers, including Medicaid, require drugs like 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[4]:

NDC[1,4]	Code Descriptor
11-Digit	25682-**0**001-01 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.[4]

Drug Administration Services

Payers may offer separate coverage and reimbursement for drug administration services. The following Current Procedural Terminology (CPT®) codes may be appropriate to report administration of SOLIRIS in physician offices and hospital outpatient facilities. Individual payer policies should be reviewed for reporting requirements:

CPT[5]	Code Descriptor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; 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 code for 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 code for 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.[6]

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious 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 PNH 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[5]	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[5]	Code Descriptor
90460	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; first or only component of each vaccine or toxoid administered
+ 90461	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; each additional vaccine or toxoid component administered (List separately in addition to code for primary procedure)
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)

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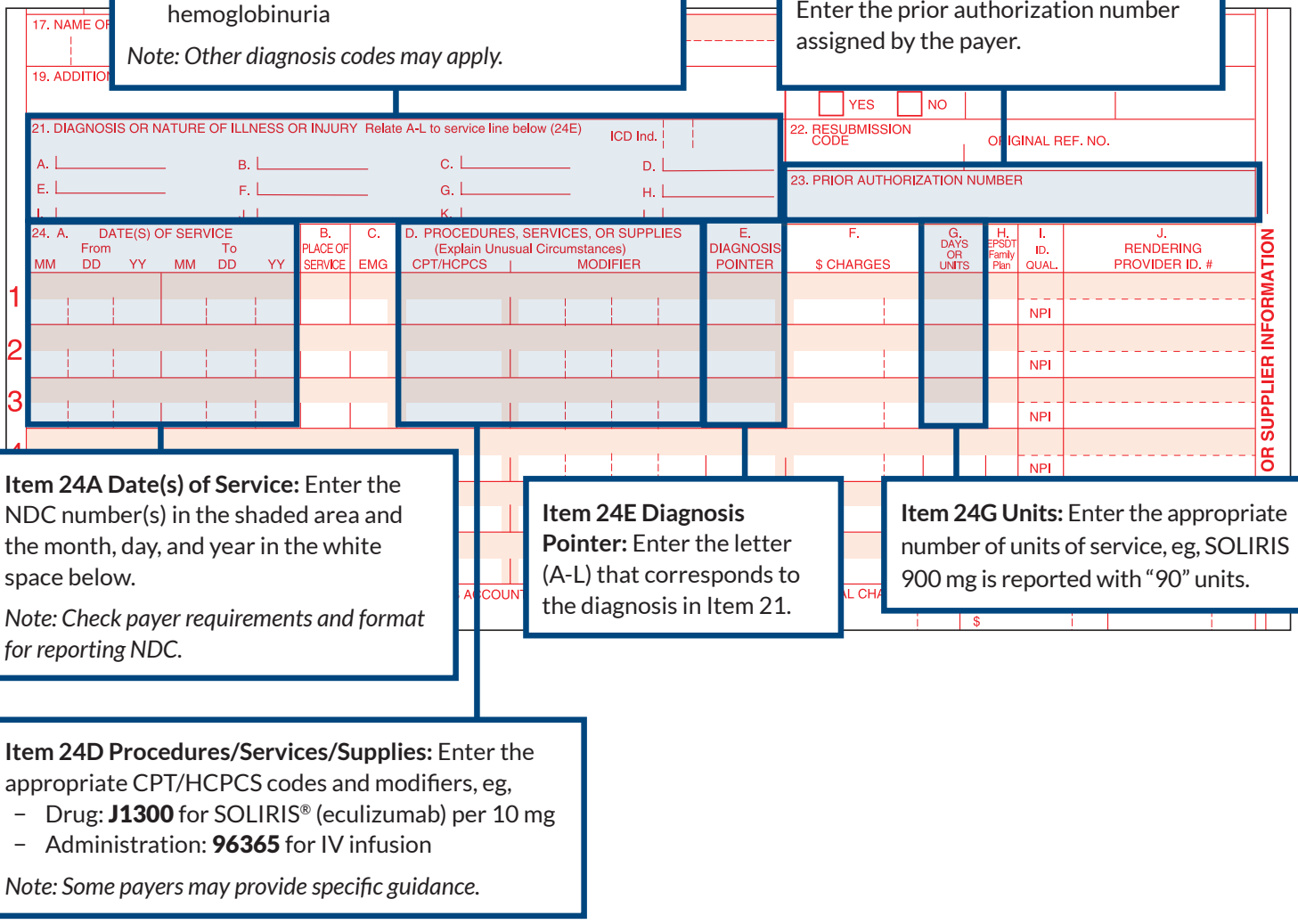
Claim Forms

Sample CMS-1500 (or the electronic equivalent 837P): Physician Office[7]

For an example of a completed CMS-1500 form, go to page 8.



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

- ICD-10-CM **D59.5** for paroxysmal nocturnal hemoglobinuria

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

Item 24G Units: Enter the appropriate number of units of service, eg, SOLIRIS 900 mg is reported with "90" units.

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

- Drug: **J1300** for SOLIRIS® (eculizumab) per 10 mg
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

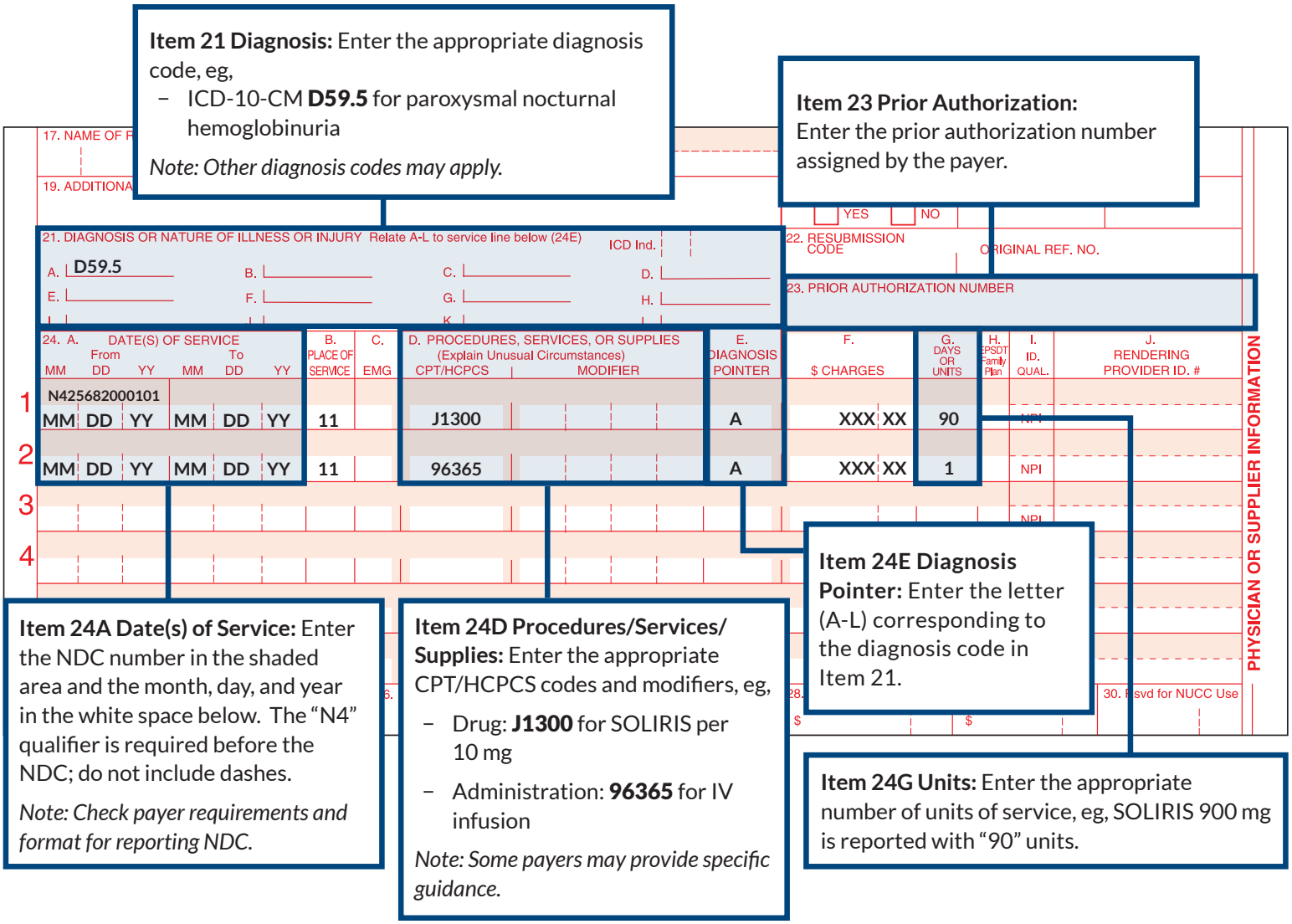
Claim Forms

Sample CMS-1500 (or the electronic equivalent 837P): Physician Office[7]

Example claim form for a SOLIRIS® (eculizumab) IV infusion:

To achieve a SOLIRIS maintenance dose of 900 mg for a patient 18 years of age and older, the following vials were used:

- 3 single-use 300 mg/30 mL vials (NDC 25682-0001-01)



Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

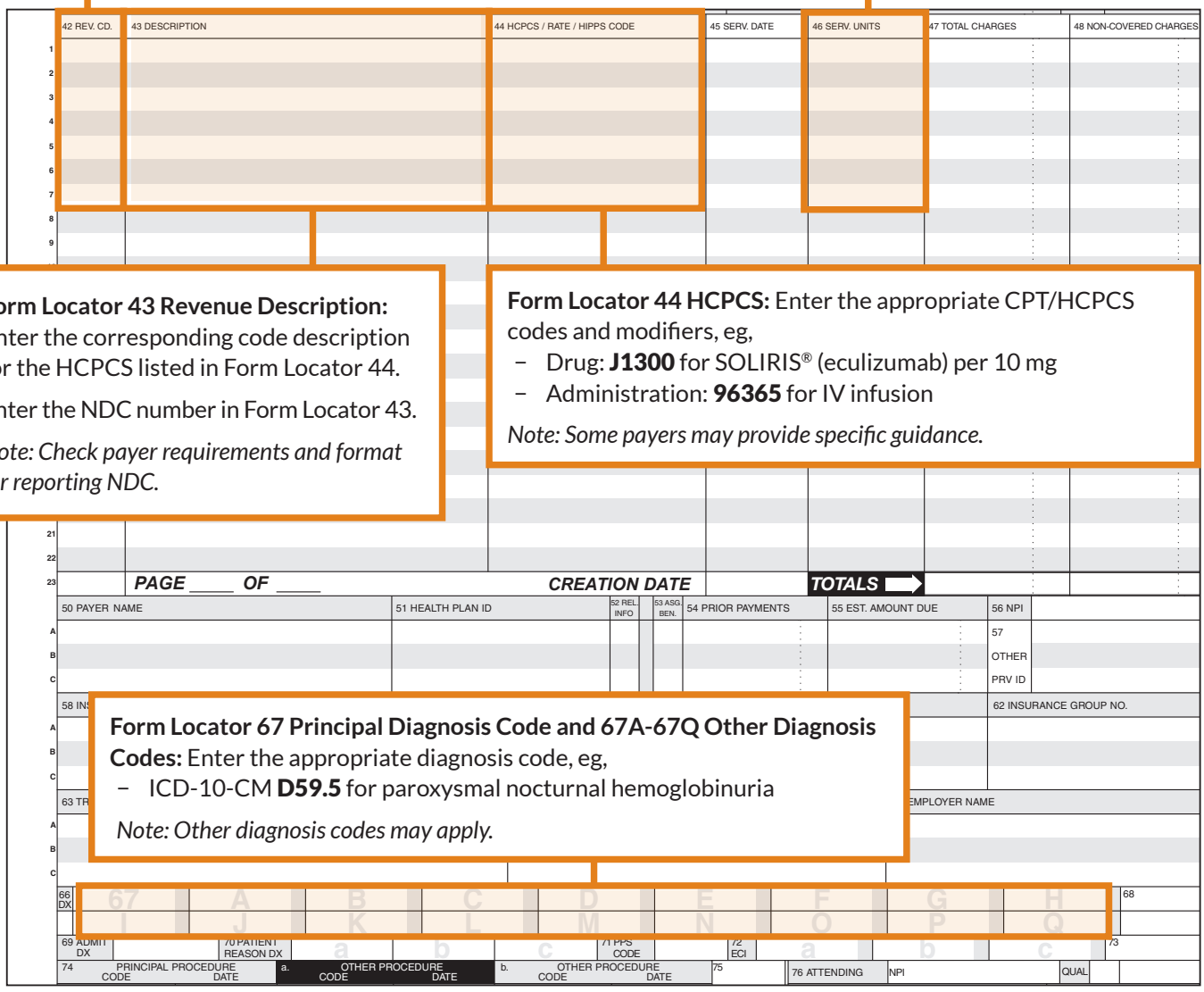
Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility[8]

For an example of a completed CMS-1450 form, go to page 10.

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,
- **0636** for SOLIRIS® (eculizumab)[9]
- **0260** for IV administration[9]

Note: Other revenue codes may apply.

Form Locator 46 Units of Service: Enter the appropriate number of units of service, eg, SOLIRIS 900 mg is reported with "90" 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: **J1300** for SOLIRIS® (eculizumab) per 10 mg
- 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 **D59.5** for paroxysmal nocturnal hemoglobinuria

Note: Other diagnosis codes may apply.

Please see Important Safety Information on pages 2-3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility[8]

Example claim form for a SOLIRIS® (eculizumab) IV infusion:

To achieve a SOLIRIS maintenance dose of 900 mg for a patient 18 years of age and older, the following vials were used:

- 3 single-use 300 mg/30 mL vials (NDC 25682-0001-01)

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,
- **0636** for SOLIRIS® (eculizumab)[9]
- **0260** for IV administration[9]

Note: Other revenue codes may apply.

Form Locator 46 Units of Service: Enter the appropriate number of units of service, eg, SOLIRIS 900 mg is reported with "90" units.

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
1	0636	SOLIRIS N425682000101	J1300	MMDDYY	90	XXX XX	
2	0260	Intravenous infusion initial, up to 1 hour	96365	MMDDYY	1	XXX XX	
3							
4							
5							
19							
20							
21							
22							
23		PAGE ____ OF ____	CREATION DATE		TOTALS		

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.

Note: Check payer requirements and format for reporting NDC.

Form Locator 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
- Drug: **J1300** for SOLIRIS per 10 mg
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

	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 INS	62 INSURANCE GROUP NO.
A		
B		
C		

	63 TR	EMPLOYER NAME
A		
B		
C		

Form Locator 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code, eg,
- ICD-10-CM **D59.5** for paroxysmal nocturnal hemoglobinuria

Note: Other diagnosis codes may apply.

66 DX	A	B	C	D	E	F	G	H	68
	D59.5								
	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

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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/

References

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ALEXION® AstraZeneca Rare Disease