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

In Adult Patients With Anti-Acetylcholine Receptor (AChR) Antibody Positive Generalized Myasthenia Gravis (gMG)

INDICATION

Soliris is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

SELECT IMPORTANT SAFETY INFORMATION[1]

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.

Please see additional Important Safety Information on page 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

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

Product Overview[1]

Soliris® (eculizumab) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Soliris is administered as an intravenous (IV) infusion (not IV push or bolus) that typically lasts about 35 minutes in adults.

Soliris is supplied as a 300 mg single-dose vial.

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

Purpose of This Guide

Alexion Pharmaceuticals, Inc. has developed the Soliris 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 call 1-888-765-4747 to speak with the Alexion OneSource™ Team.

Please see Important Safety Information on pages 1 and 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

Coding for Soliris® (eculizumab) in Anti-AChR Antibody Positive gMG

Diagnosis Coding

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

ICD-10-CM Diagnosis Code[2]	Code Descriptor
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Drug Coding

The following 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 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 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]	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.

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:

CPT Code[5]	Code Descriptor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour
96413	Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance/drug

Please see Important Safety Information on pages 1 and 10 and the full Prescribing Information for Soliris, 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 gMG 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, Y, and W-135, quadrivalent (MCV4 or MenACWY), for intramuscular use

Vaccine Administration Coding

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

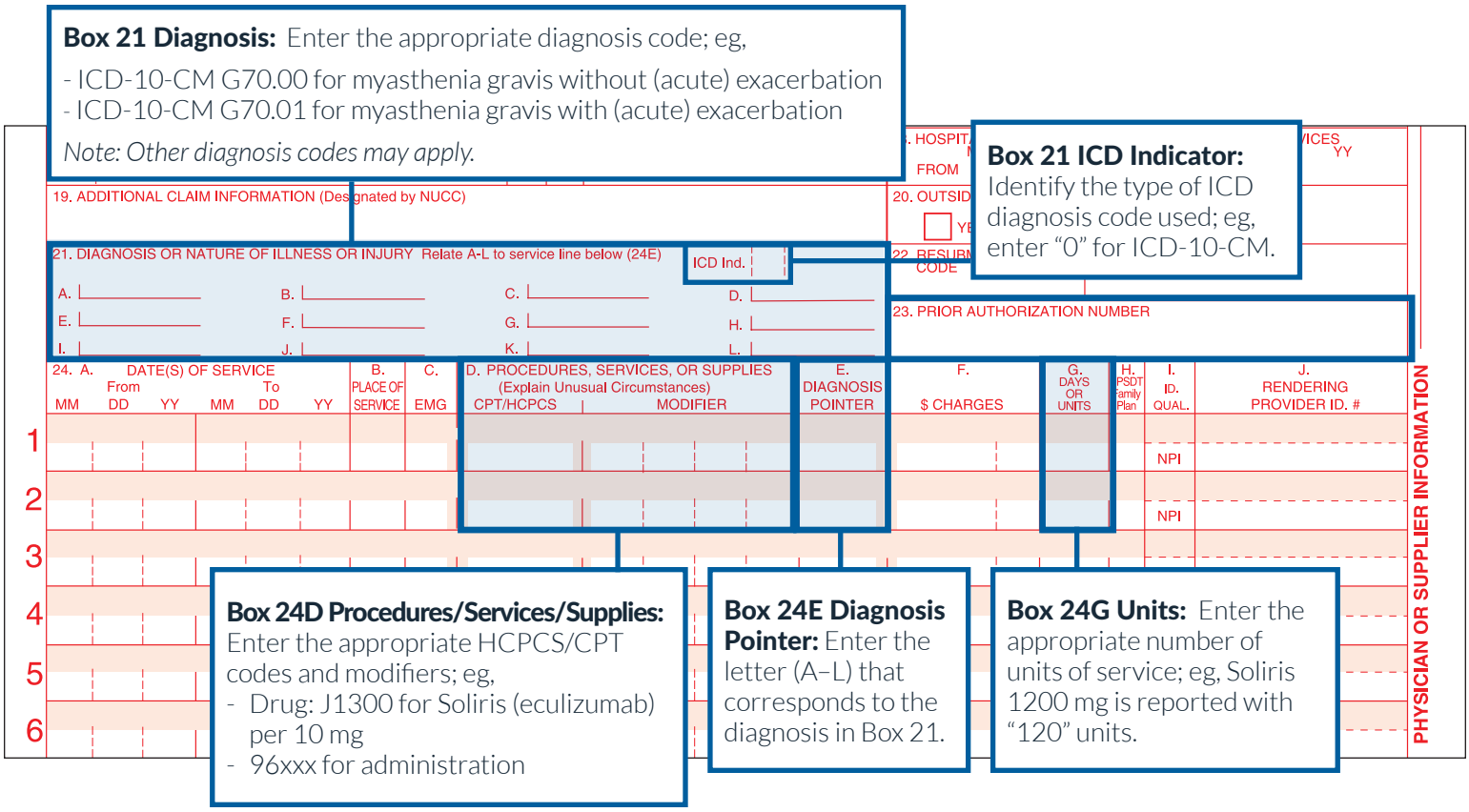
CPT Code[5]	Code Descriptor
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)

Please see Important Safety Information on pages 1 and 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

Claim Forms

Sample CMS-1500: Physician Office

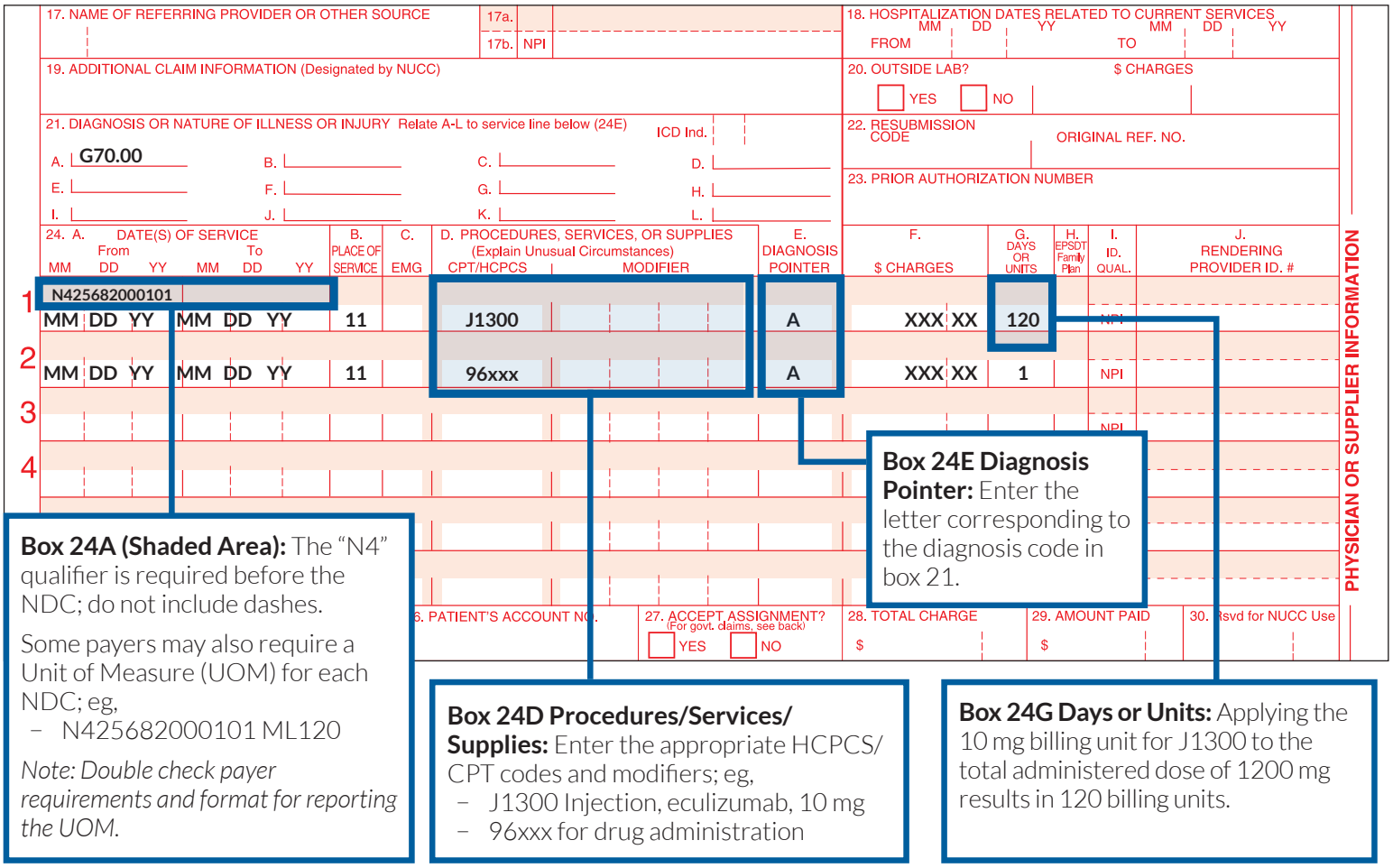
For an example of a completed CMS-1500 form, go to page 6.



Please see Important Safety Information on pages 1 and 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious 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 24D Procedures/Services/ Supplies: Enter the appropriate HCPCS/ CPT codes and modifiers; eg,

- J1300 Injection, eculizumab, 10 mg
- 96xxx for drug administration

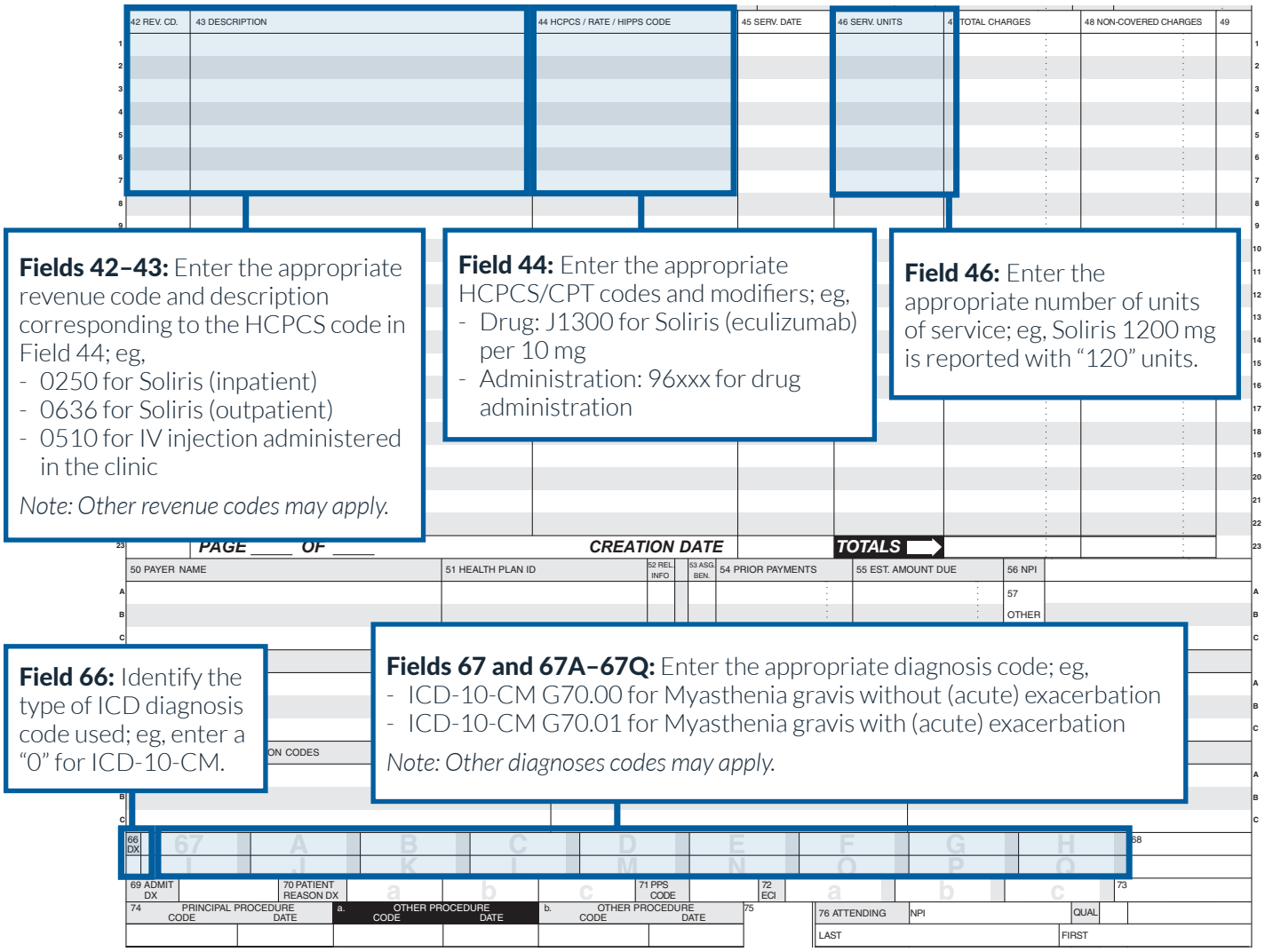
Box 24E Diagnosis Pointer: Enter the letter corresponding to the diagnosis code in box 21.

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 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

Sample CMS-1450: Hospital Clinic or Facility

For an example of a completed CMS-1450 form, go to page 8.



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 HCPCS/CPT codes and modifiers; eg,
- Drug: J1300 for Soliris (eculizumab) per 10 mg
- Administration: 96xxx for drug administration

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 G70.00 for Myasthenia gravis without (acute) exacerbation
- ICD-10-CM G70.01 for Myasthenia gravis with (acute) exacerbation

Note: Other diagnoses codes may apply.

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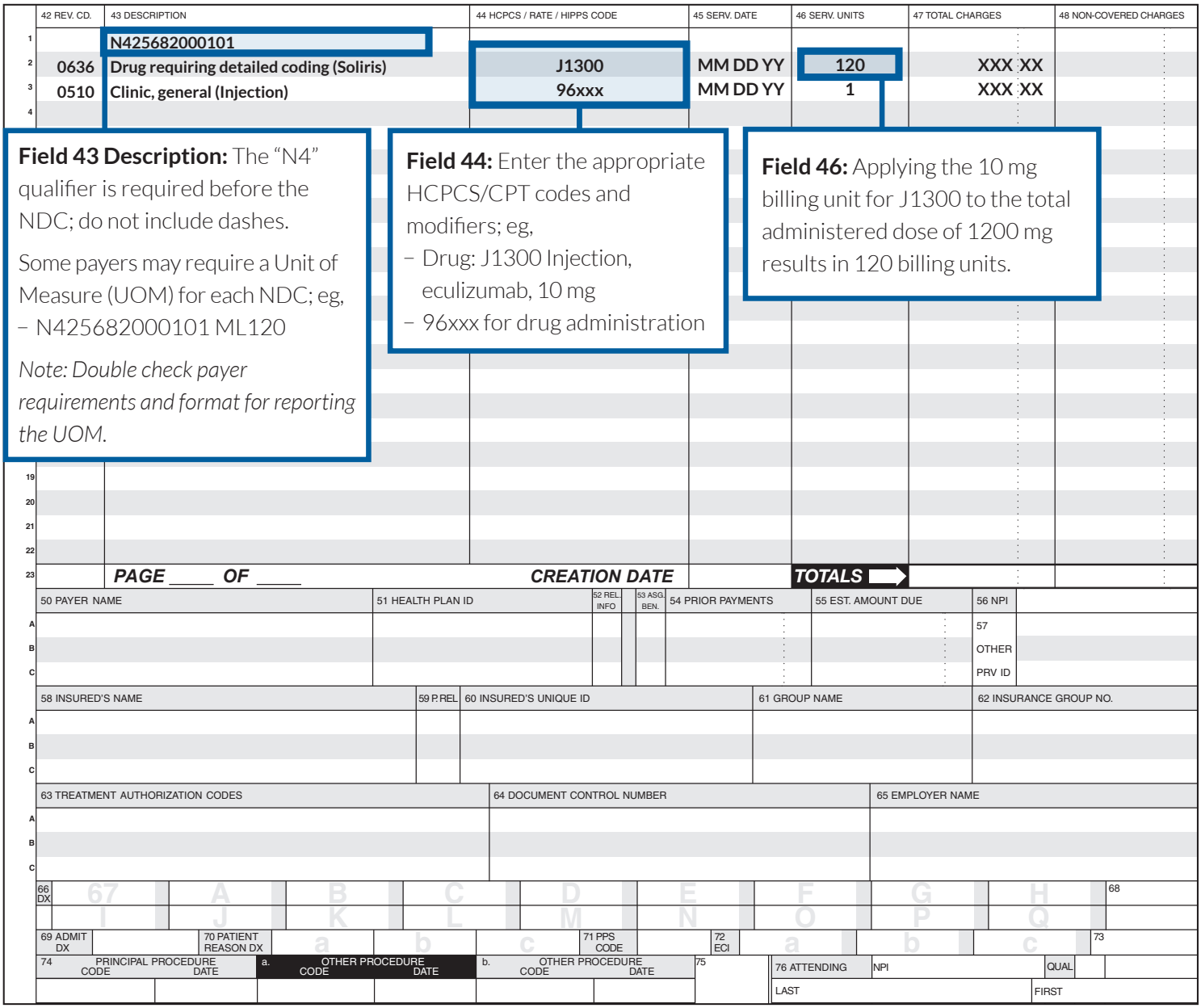
Sample CMS-1450: Hospital Clinic or Facility

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



	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	MM DD YY	120	XXX XX	
3	0510	Clinic, general (Injection)	96xxx	MM DD YY	1	XXX XX	
4							
19							
20							
21							
22							
23		PAGE ____ OF ____	CREATION DATE		TOTALS		

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

	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	

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 HCPCS/CPT codes and modifiers; eg,
- Drug: J1300 Injection, eculizumab, 10 mg
- 96xxx for drug administration

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

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OneSource™ Offers Patient Support

Contact OneSource™:

Phone:
1-888-765-4747 Monday to Friday,
8:30 AM to 5:00 PM ET

Online:
https://alexiononesource.com/

References

1. Soliris® (eculizumab) [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.
2. *2020 ICD-10 Expert for Hospitals*. Optum360; 2019. © 2019, Optum360, LLC. All rights reserved. Optum360 is a trademark of Optum360, LLC.
3. Centers for Medicare & Medicaid Services. 2020 Alpha Numeric HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File. Accessed October 19, 2020.
4. Food and Drug Administration. Future Format of the National Drug Code; Public Hearing; Request for Comments. Federal Register 83;152:38666-38668. August 7, 2018. https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-requestfor-comments. Accessed October 19, 2020.
5. *2020 CPT Professional*. American Medical Association; 2019. CPT © 2019 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Please see Important Safety Information on pages 1 and 10 and the full Prescribing Information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

SELECT IMPORTANT SAFETY INFORMATION (continued)

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.

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.

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 reaction in the gMG placebo-controlled clinical trial (≥10%) is: musculoskeletal pain.

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