

PRESCRIBER START FORM – NEUROLOGY

EMAIL: OneSource@Alexion.com

PHONE: 1.888.765.4747 8:30 AM to 8 PM ET Monday-Friday

FAX: 1.800.420.5150

MAIL: 100 College St., New Haven, CT 06510

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

ONESOURCE[®]
Personalized Patient Support from Alexion

OneSource™ is a complimentary, personalized patient support program offered by Alexion. It's designed to support patients' specific needs throughout treatment. For more information, visit www.AlexionOneSource.com.



INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS: To enroll your patient in OneSource™, please follow these steps:

- 1 Have your patient complete all required sections and read the Authorization to Share Health Information on the Patient Start Form
- 2 Complete all required sections on **PAGE 1** and sign the Prescriber Certification in Step 8 on **PAGE 2**
 - If applicable, fill out the SOLIRIS prescription order form (**PAGE 2**) and meningococcal vaccination series order form (**PAGE 3**)
- 3 Email or fax **PAGES 1-3 of the completed start form** and **copies of the front and back of the patient's insurance and pharmacy coverage cards** to OneSource. See the email address and fax number at the top of the form.

Contact OneSource if you have any questions while completing the forms.

Fields in red are required.

STEP 1: PATIENT INFORMATION

PATIENT NAME (FIRST, LAST) PATIENT EMAIL DATE OF BIRTH (MM/DD/YYYY) GENDER: MALE FEMALE OTHER

STEP 2: CLINICAL DIAGNOSIS

SOLIRIS is FDA approved for antibody positive status. If a payer requires prior authorization and/or has a clinical policy, they may require proof of antibody status.

- GENERALIZED MYASTHENIA GRAVIS (gMG) NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) **ANTIBODY STATUS:** ANTI-AChR ANTIBODY POSITIVE (gMG) ANTI-AQP4 ANTIBODY POSITIVE (NMOSD) UNKNOWN (CONTACT ONESOURCE FOR QUESTIONS)

STEP 3: INSURANCE INFORMATION (OPTIONAL)

NOTE: You may attach copies of the front and back of the patient's insurance card(s) in lieu of completing this section.

<input type="checkbox"/> SEE COPIES OF PATIENT INSURANCE CARD(S) ATTACHED <input type="checkbox"/> CHECK HERE IF PATIENT DOES NOT HAVE INSURANCE		PRIMARY MEDICAL INSURANCE	SECONDARY MEDICAL INSURANCE	PHARMACY COVERAGE
INSURANCE PROVIDER				
INSURANCE PHONE #				
CARDHOLDER NAME				
CARDHOLDER DATE OF BIRTH				
MEMBER ID				
POLICY #				
GROUP #				
BIN/PCN #				

STEP 4: HEALTHCARE PRESCRIBER INFORMATION

FIRST NAME	LAST NAME	PROVIDER EMAIL
ADDRESS		PHONE NUMBER
CITY	STATE	ZIP
PRACTICE NAME	TAX ID #	NPI #
OFFICE CONTACT NAME	EMAIL	FAX NUMBER

STEP 5: PREFERRED SITE OF CARE (OPTIONAL)

- YES, PLEASE PROVIDE ASSISTANCE LOCATING AN INFUSION SITE.** PLEASE COORDINATE DIRECTLY WITH: HEALTHCARE PROVIDER PATIENT
- NO, ASSISTANCE IS NOT NEEDED.** PATIENT WILL BE INFUSED AT: PRESCRIBER'S OFFICE PATIENT'S HOME INPATIENT
- OUTPATIENT OFF CAMPUS OUTPATIENT ON CAMPUS

SITE OF CARE NAME	NPI #	TAX ID #
ADDRESS		
CITY	STATE	ZIP
OFFICE CONTACT FOR FOLLOW-UP		PHONE NUMBER

Please see Indications & Important Safety Information on page 4 and full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious meningococcal infections, also available on www.SOLIRIS.net.

US/SOL-g/0538 03/22

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PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)

DATE OF BIRTH (MM/DD/YYYY)

STEP 6: CLINICAL INFORMATION (OPTIONAL)

CHECK ALL PREVIOUS GENERALIZED MYASTHENIA GRAVIS (gMG) THERAPIES:

- AZATHIOPRINE PLASMAPHERESIS RITUXIMAB
 IVIg PREDNISONE OTHER
 MYCOPHENOLATE MOFETIL PYRIDOSTIGMINE

CHECK ALL PREVIOUS NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) THERAPIES:

- AZATHIOPRINE MITOXANTRONE SATRALIZUMAB
 CYCLOPHOSPHAMIDE MYCOPHENOLATE MOFETIL STEROID
 INEBILIZUMAB RITUXIMAB OTHER
 METHOTREXATE

MGFA CLASSIFICATION:

NUMBER OF RELAPSES IN LAST 12 MONTHS:

24 MONTHS:

CURRENT MG-ADL SCORE:

EDSS SCORE:

Abbreviations: AChR, acetylcholine receptor; EDSS, Expanded Disability Status Scale; gMG, generalized myasthenia gravis; IVIg, intravenous immunoglobulin; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; NMOSD, neuromyelitis optica spectrum disorder.

STEP 7: PRESCRIPTION (OPTIONAL)

YOU MAY USE THIS SECTION TO PROVIDE A PRESCRIPTION FOR SOLIRIS, OR YOU MAY PROVIDE A SEPARATE PRESCRIPTION.

- SOLIRIS® (eculizumab) NDC # 25682-0001-01/HCPCS CODE: J1300 PER UNIT ICD 10-CM MG (G70.00)/NMOSD (G36.0)

INDUCTION DOSING

WEEKS 1-4:

RECOMMENDED DOSE: 900 mg WEEKLY FOR FIRST 4 WEEKS:

- DISPENSE (12) 300-mg SINGLE-DOSE SOLIRIS VIALS

INFUSION INSTRUCTIONS:

WEEK 5:

RECOMMENDED DOSE: 1200 mg 1 WEEK AFTER PREVIOUS DOSE

- DISPENSE (4) 300-mg SINGLE-DOSE SOLIRIS VIALS

MAINTENANCE TREATMENT

WEEKS 6+:

RECOMMENDED DOSE: 1200 mg EVERY 2 WEEKS

- DISPENSE (_____) 300-mg SINGLE-DOSE SOLIRIS VIALS

REFILLS: _____

INFUSION INSTRUCTIONS:

HAS YOUR PATIENT RECEIVED A COMPLETE SERIES OF MENINGOCOCCAL VACCINATIONS? *See ACIP guidelines below

Patient has received or is scheduled to receive the required vaccinations per ACIP guidelines.

Please complete the following:

MenACWY		MenB	
YES	1st Dose Date: ____/____/____	1st Dose Date: ____/____/____	NO
	Mfr: <input type="checkbox"/> Menveo <input type="checkbox"/> Menactra <input type="checkbox"/> MenQuadfi	Mfr: <input type="checkbox"/> Bexsero <input type="checkbox"/> Trumenba	
	2nd Dose Date: ____/____/____	2nd Dose Date: ____/____/____	
	Mfr: <input type="checkbox"/> Menveo <input type="checkbox"/> Menactra <input type="checkbox"/> MenQuadfi	Mfr: <input type="checkbox"/> Bexsero <input type="checkbox"/> Trumenba	
SIGN THE PRESCRIBER CERTIFICATION BELOW AND SKIP PAGE 3		3rd Dose Date: ____/____/____ (3rd dose - Trumenba ONLY)	

SIGN THE PRESCRIBER CERTIFICATION BELOW AND CONTINUE TO PAGE 3

You may use the next page to provide and sign a prescription for vaccines, or you may provide a separate prescription.

*The current ACIP guidelines recommend a regimen of MenACWY AND MenB doses prior to starting a complement inhibitor treatment.

STEP 8: PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) I am prescribing SOLIRIS for the patient identified above based on my clinical judgment that it is medically necessary for the diagnosis identified on this form and I will be supervising the patient's treatment; (ii) I am authorized under applicable law to prescribe SOLIRIS and I have verified and complied with all applicable prescription requirements; (iii) I am authorizing Alexion to forward the patient's prescription to a pharmacy; (iv) I am under no obligation to prescribe SOLIRIS and I have not received, nor will I receive, any benefit from Alexion for prescribing SOLIRIS; and (v) the information provided on this form is complete, current, and accurate to the best of my knowledge. I also acknowledge that Alexion will use and share the personal data collected about me (as the prescriber) in accordance with the Privacy Notice on the Alexion website at <https://alexion.com/Legal#privacy>.

SIGN ONE



PRESCRIBER'S SIGNATURE (NO STAMPS) - DISPENSE AS WRITTEN

DATE (MM/DD/YYYY)

PRESCRIBER'S SIGNATURE (NO STAMPS) - MAY SUBSTITUTE

DATE (MM/DD/YYYY)

Please verify your local prescribing requirements (eg, New York prescribers must provide a separate prescription).

Please see Indications & Important Safety Information on page 4 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections, also available on www.SOLIRIS.net.

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MENINGOCOCCAL VACCINATION SERIES PRESCRIBER ORDER FORM

PATIENT NAME (FIRST, MIDDLE INITIAL, LAST)		PATIENT DATE OF BIRTH (MM/DD/YYYY)	
ADDRESS	CITY	STATE	ZIP
PHONE NUMBER	HEIGHT	WEIGHT	

CLINICAL INFORMATION

Primary Diagnosis Description: Encounter for Immunization

ICD-10 CODE: Z23

MENINGOCOCCAL VACCINATIONS ARE INDICATED FOR ADULTS, INCLUDING PEOPLE OVER 55 YEARS OF AGE, WHEN ON A COMPLEMENT INHIBITOR TREATMENT.

The ACIP recommends a regimen of MenACWY AND MenB doses prior to starting a complement inhibitor treatment. Vaccines should be initiated at least 2 weeks prior to first dose of SOLIRIS. There are two (2) types of meningococcal vaccines available in the United States, with different dosing schedules.

MenACWY
One (1) required from this group

AND

MenB
One (1) required from this group

VACCINES ARE NOT INTERCHANGEABLE. PATIENT MUST RECEIVE THE SAME PRODUCT FOR ALL DOSES. FOR THE FULL VACCINE SCHEDULE, PLEASE REFER TO THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) VACCINE RECOMMENDATIONS OR TO ALEXION MEDICAL INFORMATION.

Three quadrivalent meningococcal conjugate (MenACWY) vaccines are currently licensed and available in the United States.

INDICATE VACCINE THE PATIENT NEEDS TO RECEIVE:

- Menactra (meningococcal groups A, C, W, and Y polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D)) 907340
- Menveo (meningococcal groups A, C, W, and Y oligosaccharide diphtheria CRM conjugate vaccine (MenACWY-CRM)) 907340
- MenQuadfi (meningococcal groups A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT)) 90619

Two serogroup B meningococcal (MenB) vaccines are currently licensed and available in the United States.

INDICATE VACCINE THE PATIENT NEEDS TO RECEIVE:

- Bexsero (MenB-4C) 90620
- Trumenba (MenB-FHbp) 90621

DOSING SCHEDULE

MenACWY	MenB
Dose 1: Day 0	Dose 1: Day 0
Dose 2: At least 8 weeks after Day 0	Dose 2: For Bexsero: At least (or greater than or equal to) 1 month after Day 0 For Trumenba: 1-2 months after Day 0
	Dose 3 (Trumenba only): 6 months after Day 0

NOTE: ALL VACCINES LISTED ABOVE ARE ADMINISTERED INTRAMUSCULARLY AT A DOSE OF 0.5 mL

ANCILLARY ORDERS (HOME INFUSION ONLY – USE AS NEEDED)

Anaphylaxis Kit

The following items will be dispensed:

- Diphenhydramine 50 mg/mL 1 mL vial x 1. Inject 25 mg IM PRN for allergic reaction. May repeat x 1 dose in 15 min PRN if no improvement
- NS 500 mL bag x 1. Infuse 500 mL IV at KVO rate PRN anaphylaxis
- Epinephrine ampule/vial 1 mg/mL (1:1000) 1 mL x 2 ampules/vials. Inject 0.3 mg SQ PRN for adverse reaction. May repeat x 1 dose in 5 to 15 min PRN

General Anaphylaxis Instructions

Administer emergency medications as ordered. Administer epinephrine as above and repeat dose if necessary. Administer injectable diphenhydramine as above and repeat dose if necessary. Place peripheral IV and administer NS. Initiate CPR if needed. Call EMS (activate the emergency medical system). Monitor vital signs—elevate legs if hypotensive. Notify prescriber and Nursing Director or pharmacist.

PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) based on my clinical judgment, the vaccines identified are medically necessary for the patient and diagnosis identified on this form; (ii) I am authorized under applicable law to prescribe the vaccines identified and I have verified and complied with all applicable prescription requirements; (iii) I am authorizing Alexion to forward the patient's prescription(s) to a pharmacy; (iv) I am under no obligation to prescribe the vaccines identified and I have not received, nor will I receive, any benefit from Alexion; and (v) the information provided on this form is complete, current, and accurate to the best of my knowledge.

May substitute

PRESCRIBER SIGNATURE (NO STAMPS)

DATE (MM/DD/YYYY)

Please verify your local prescribing requirements (eg, New York prescribers must provide a separate prescription)

Please see Indications & Important Safety Information on page 4 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections, also available on www.SOLIRIS.net.

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INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS[®] (eculizumab)

INDICATIONS

Generalized Myasthenia Gravis (gMG)

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

Neuromyelitis Optica Spectrum Disorder (NMOSD)

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

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.

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 ($\geq 10\%$) is: musculoskeletal pain.

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

Please see full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious meningococcal infections, also available on www.SOLIRIS.net.

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ALEXION[®]
AstraZeneca Rare Disease

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- 1 Complete all the required information (in red) on **PAGE 1** and read the Authorization to Share Health Information on **PAGE 2**
- 2 Sign the Authorization to Share Health Information section on **PAGE 1**
- 3 Email or fax **PAGE 1 of the form** and **copies of the front and back of your insurance and pharmacy coverage cards** to OneSource. See the email address and fax number above.

Be sure to complete all required fields and sign and date the form. If information is incomplete, it could delay our ability to enroll you in OneSource. OneSource can start offering you personalized support once you submit this form fully and correctly completed.

Note: You can choose not to sign this form. However, we cannot provide personalized support without your signed authorization.

Fields in red are required.

Contact OneSource if you have any questions while completing the forms.

PATIENT INFORMATION

PATIENT NAME (FIRST, MIDDLE INITIAL, LAST)		DATE OF BIRTH (MM/DD/YYYY)	
ADDRESS			
CITY		STATE	ZIP
PRIMARY PHONE NUMBER <input type="checkbox"/> MOBILE <input type="checkbox"/> HOME	OK TO SEND A TEXT MESSAGE? <input type="checkbox"/> YES <input type="checkbox"/> NO OK TO LEAVE A PHONE MESSAGE? <input type="checkbox"/> YES <input type="checkbox"/> NO	PATIENT DIAGNOSIS	
PREFERRED LANGUAGE <input type="checkbox"/> ENGLISH <input type="checkbox"/> SPANISH <input type="checkbox"/> OTHER _____	PATIENT EMAIL <input type="checkbox"/> NONE		
LEGAL PATIENT REPRESENTATIVE NAME: _____ PHONE: _____	DESIGNATED PATIENT REPRESENTATIVE NAME: _____ PHONE: _____		
RELATIONSHIP TO PATIENT	RELATIONSHIP TO PATIENT		
EMAIL <input type="checkbox"/> NONE	EMAIL <input type="checkbox"/> NONE		

PRESCRIBING PHYSICIAN'S INFORMATION

PROVIDER NAME	PROVIDER PHONE NUMBER	PROVIDER EMAIL
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AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION

By signing below, I acknowledge that I have read and agree to the Authorization to Share Health Information terms on the next page.

SIGN HERE



SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

CONSENT FOR PROMOTIONAL COMMUNICATIONS (OPTIONAL)

INITIAL FOR CONSENT

I give Alexion and companies working at Alexion's direction permission to use my contact information to provide promotional information to me about Alexion products, services, programs, or other topics that Alexion thinks may interest me. I understand that Alexion will use and share my information in accordance with the Privacy Notice on the Alexion website at <https://alexion.com/Legal#privacy>.

CONSENT FOR AUTOMATED TEXT COMMUNICATIONS (OPTIONAL)

By signing below, I give Alexion and companies working at Alexion's direction permission to use automated text (SMS) messages to provide patient support services and to provide information to me about Alexion products, services, programs, or other topics that Alexion thinks may interest me. I understand that (i) I am not required to consent to receiving text messages as a condition of any purchase of Alexion products or enrollment in these programs; (ii) my telecommunication services provider may charge me for any text messages that I receive from Alexion; and (iii) I may opt out of receiving automated text messages from Alexion at any time without affecting my enrollment in these programs.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

CONSENT FOR COPAY PROGRAM (OPTIONAL)

By signing below, I acknowledge that I have read and agree to the Alexion OneSource™ CoPay Program eligibility terms on the next page.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

Please see Indications & Important Safety Information on page 3 and full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections, also available on www.SOLIRIS.net.

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AUTHORIZATION TO SHARE HEALTH INFORMATION

Alexion Pharmaceuticals, Inc. (“Alexion”) offers patient services that include (but are not limited to) educational resources, case management support, and financial assistance for eligible patients.

By signing on the prior page, I give permission for my healthcare providers, health plans, or other insurance programs, pharmacies, and other healthcare service providers (“My Healthcare Entities”) to share information, including protected health information, relating to my medical condition, treatment, and health insurance coverage (collectively “My Information”) with Alexion and companies working at its direction so that Alexion may use and disclose My Information to:

- review my eligibility for benefits for treatment with an Alexion product;
- coordinate treatment with an Alexion product, as well as related services, such as arranging home infusion services or vaccine services;
- access my credit information and information from other sources to estimate my income, if needed to assess eligibility for financial assistance programs;
- remove identifiers from My Information and combine such resulting information with other information for research, regulatory submissions, business improvement projects, and publication purposes; and
- contact me about market research or clinical studies.

I understand that My Healthcare Entities may receive payment from Alexion in exchange for sharing My Information.

I understand that My Information is also subject to the Alexion Privacy Notice available at <https://alexion.com/Legal#privacy>, and that the Alexion Privacy Notice provides additional information about Alexion’s privacy practices and the rights that may be available to me. Although Alexion has implemented privacy and security controls designed to help protect My Information, I understand that once My Information has been disclosed to Alexion, U.S. and state laws may not apply and may no longer protect the information.

I understand that I may cancel my authorization at any time by mailing a letter to Alexion OneSource™ Patient Support Program, 121 Seaport Blvd, Boston, MA 02210 or by emailing OneSource@Alexion.com. I also understand that canceling my authorization will not affect any use or disclosure of My Information that occurred before Alexion received notice of my cancellation.

This Authorization expires ten (10) years from the date next to my signature, unless I revoke it sooner, or unless a shorter time frame is required by applicable law. I understand I have a right to receive a copy of this authorization after it is signed.

OneSource™ Services

Alexion services and support are subject to change. Participation is voluntary, and person(s) may be removed from Alexion services for code of conduct violations.

CoPay Program Eligibility

By participating in the Alexion OneSource CoPay Program, participants acknowledge that they understand and agree with the complete program terms and conditions available at <https://alexiononesource.com/CoPay> or on request by contacting OneSource at 1.888.765.4747.

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INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS[®] (eculizumab)

INDICATIONS

What is SOLIRIS?

SOLIRIS is a prescription medicine used to treat:

- adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with a disease called neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

It is not known if SOLIRIS is safe and effective in children with gMG or NMOSD.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SOLIRIS?

SOLIRIS is a medicine that affects your immune system and can lower the ability of your immune system to fight infections.

- SOLIRIS increases your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.**

- You must receive meningococcal vaccines at least 2 weeks before your first dose of SOLIRIS if you are not vaccinated.
- If your doctor decided that urgent treatment with SOLIRIS is needed, you should receive meningococcal vaccination as soon as possible.
- If you have not been vaccinated and SOLIRIS therapy must be initiated immediately, you should also receive two weeks of antibiotics with your vaccinations.
- If you had a meningococcal vaccine in the past, you might need additional vaccination. Your doctor will decide if you need additional vaccination.
- Meningococcal vaccines reduce but do not prevent all meningococcal infections. Call your doctor or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms, and eyes sensitive to light.

Your doctor will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last SOLIRIS dose. It is important to show this card to any doctor or nurse to help them diagnose and treat you quickly.

SOLIRIS is only available through a program called the SOLIRIS REMS. Before you can receive SOLIRIS, your doctor must enroll in the SOLIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a **Patient Safety Card** about the symptoms and your risk of meningococcal infection

Please see full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections, also available on www.SOLIRIS.net.

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(as discussed above); and make sure that you are vaccinated with the meningococcal vaccine and, if needed, get revaccinated with the meningococcal vaccine. Ask your doctor if you are not sure if you need to be revaccinated.

SOLIRIS may also increase the risk of other types of serious infections. Certain people may be at risk of serious infections with gonorrhea. Certain fungal infections (*Aspergillus*) may occur if you take SOLIRIS and have a weak immune system or a low white blood cell count.

Who should not receive SOLIRIS?

Do not receive SOLIRIS if you have a meningococcal infection or have not been vaccinated against meningitis infection unless your doctor decides that urgent treatment with SOLIRIS is needed.

Before you receive SOLIRIS, tell your doctor about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if SOLIRIS will harm your unborn baby or if it passes into your breast milk.

Tell your doctor about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment. It is important that you have all recommended vaccinations before you start SOLIRIS, receive 2 weeks of antibiotics if you immediately start SOLIRIS, and stay up-to-date with all recommended vaccinations during treatment with SOLIRIS.

What are the possible side effects of SOLIRIS?

SOLIRIS can cause serious side effects including serious infusion-related reactions. Tell your doctor or nurse right away if you get any of these symptoms during your SOLIRIS infusion: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out. If you have an infusion-related reaction to SOLIRIS, your doctor may need to infuse SOLIRIS more slowly, or stop SOLIRIS.

The most common side effects in people with gMG treated with SOLIRIS include: muscle and joint (musculoskeletal) pain.

The most common side effects in people with NMOSD treated with SOLIRIS include: common cold (upper respiratory infection), pain or swelling of your nose or throat (nasopharyngitis), diarrhea, back pain, dizziness, flu like symptoms (influenza) including fever, headache, tiredness, cough, sore throat, and body aches, joint pain (arthralgia), throat irritation (pharyngitis), and bruising (contusion).

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of SOLIRIS. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088.