ZILBRYSQ®
(zilucoplan) Injection

Prior Authorization Checklist

Your patient's health plan may require a prior authorization (PA) before ZILBRYSQ (zilucoplan) coverage can be approved. A common reason for coverage denial is incomplete or missing information on the request form. Contact the individual payer for requirements and clinical coverage guidelines for ZILBRYSQ, if available. This checklist is provided as an educational resource regarding common PA requirements for ZILBRYSQ.

1 Diagnosis Code[1,*]

☐ G70.00 Myasthenia gravis without (acute) exacerbation ☐ G70.01 Myasthenia gravis with (acute) exacerbation

*These diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement. They include potential codes for the FDA-approved indication for ZILBRYSQ. Please consult the most recent version of the ICD-10-CM for a full list of myasthenia gravis (MG) codes.

2 Clinical Information

Provide relevant supporting documentation, including chart notes and lab tests.

MGFA Clinical Classification†: _____ Date of latest assessment: _____

MGFA Clinical Classification at diagnosis: _____ Date of initial assessment: _____

MG-ADL score: _____ Date of assessment: _____

QMG score: _____ Date of assessment: _____

Comorbidities: _____

Serological and electrophysiologic testing

AChR autoantibody test: ☐ Positive ☐ Negative ☐ Not known

☐ Repetitive nerve stimulation test (result): _____ Date of assessment: _____

☐ Single fiber electromyography test (result): _____ Date of assessment: _____

†ZILBRYSQ was studied in adult patients ranging from MGFA Clinical Classification II to IV.[2]

AChR=acetylcholine receptor; FDA=Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; QMG=Quantitative Myasthenia Gravis.

INDICATION

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

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.**
- **Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for signs of meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

Please refer to pages 3 and 4 for additional Important Safety Information.
Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.

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Prior Authorization Checklist (cont'd)

3 Vaccination History[3]

ZILBRYSQ is available only through a restricted program called ZILBRYSQ REMS.

Document patient's meningococcal vaccinations, including dates of initial dose, second dose, and third dose, if applicable. PANTHERx Rare will assess patients' vaccination status and assist patients with accessing REMS-required vaccinations, if needed.

Vaccination	Date of initial dose	Date of second dose	Date of third dose (if applicable)
☐ MenACWY			
☐ MenB-4C or MenB-FHbp			

Patients should complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to receiving the first dose of ZILBRYSQ. If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with both MenACWY and MenB vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis.[2]

4 Medication History[4-11]

Document medication history for treatment of MG, including treatment category, therapy name, duration of treatment, reason for discontinuation, if applicable (eg, inadequate response, intolerance), and associated contraindications, if applicable.

Treatment category	Drug/therapy name(s)	Treatment duration	Reason for discontinuation	Associated contraindications
☐ FcRn receptor antagonists (eg, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, rozanolixizumab-noli)				
☐ Monoclonal antibodies (eg, eculizumab, ravulizumab-cwvz, rituximab)				
☐ AChE inhibitors (eg, pyridostigmine)				
☐ Oral corticosteroids (eg, prednisone)				
☐ Non-steroidal ISTs (eg, azathioprine, cyclosporine, mycophenolate)				
☐ IVIg (eg, Bivigam®, Flebogamma®, Gammagard® S/D, Gammagard Liquid®, Gammaked™ , Gammaplex®, Gamunex®-C, Octagam®, Privigen®)				
☐ Other immunomodulatory therapy (eg, PLEX, SCIg)				

AChE=acetylcholinesterase; ACIP=Advisory Committee on Immunization Practices; FcRn=neonatal Fc receptor; IST=immunosuppressive therapy; IVIg=intravenous immunoglobulin; MenACWY=quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate vaccine; MenB=serogroup B meningococcal vaccines; MenB-4C=4-component meningococcal group B; MenB-FHbp=meningococcal serogroup B factor H binding protein. MG=myasthenia gravis; PLEX=plasma exchange; REMS=Risk Evaluation and Mitigation Strategy; SCIg=subcutaneous immunoglobulin.

Please refer to pages 3 and 4 for Important Safety Information.
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Prior Authorization Checklist (cont'd)

5 Prescribed Dose Options[2,*]

- ☐ 16.6 mg once daily (body weight <56 kg)
- ☐ 23.0 mg once daily (body weight ≥56 kg to <77 kg)
- ☐ 32.4 mg once daily (body weight ≥77 kg)

*Provide clinical rationale if prescribed dose is different from body weight recommendations.

6 Reauthorization

If the patient has already been approved for ZILBRYSQ under this plan, document the following:

- ☐ Change in MGFA Clinical Classification: _____
- ☐ Change in MG-ADL score: _____
- ☐ Change in QMG score: _____

PANTHERx RARE

To send a prescription to PANTHERx Rare or for more information, call 833-418-7760, fax 412-567-6135, or visit pantherxrare.com.

ucb RRE Rare Reimbursement Executive

If you have questions or for more information, please contact your RRE.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.**
- **Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by *N. meningitidis*, even if they develop antibodies following vaccination. Monitor patients for signs of meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

CONTRAINDICATIONS

ZILBRYSQ is contraindicated in patients with unresolved *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. The use of ZILBRYSQ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; QMG=Quantitative Myasthenia Gravis.

Please refer to the next page for additional Important Safety Information.
Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Serious Meningococcal Infections (cont'd)

Complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with both MenACWY and MenB vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

ZILBRYSQ REMS

Due to the risk of meningococcal infections, ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS.

Under the ZILBRYSQ REMS, prescribers must enroll in the program. 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 vaccines. Additional information on the REMS requirements is available at www.ZILBRYSQREMS.com or 1-877-414-8353.

Other Infections

ZILBRYSQ 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*. Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae type b* (Hib) infections according to ACIP guidelines. Persons receiving ZILBRYSQ are at increased risk for infections due to these bacteria, even after vaccination.

Pancreatitis And Other Pancreatic Conditions

Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Patients should be informed of this risk before starting ZILBRYSQ. Obtain lipase and amylase levels at baseline before starting treatment with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of gMG patients treated with ZILBRYSQ) were injection site reactions, upper respiratory tract infections, and diarrhea.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.
For more information about ZILBRYSQ, visit ZILBRYSQhcp.com.

For additional information, contact UCBCares® at 1-844-599-CARE (2273).

ACIP=Advisory Committee on Immunization Practices; gMG=generalized myasthenia gravis; REMS=Risk Evaluation and Mitigation Strategy.

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed November 13, 2023. https://www.cms.gov/files/zip/2023-code-tables-tabular-and-index-updated-01/11/2023.zip. **2.** ZILBRYSQ [prescribing information]. Smyrna, GA: UCB, Inc. **3.** Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep*. 2020;69(9):1-41. doi:10.15585/mmwr.rr6909a1. **4.** Farmakidis C, Pasnoor M, Dimachkie MM, Barohn RJ. Treatment of myasthenia gravis. *Neurol Clin*. 2018;36(2):311-337. **5.** Menon D, Bril V. Pharmacotherapy of generalized myasthenia gravis with special emphasis on newer biologicals. *Drugs*. 2022;82(8):865-887. **6.** VYVGART [prescribing information]. Boston, MA: argenx US, Inc. **7.** VYVGART Hytrulo [prescribing information]. Boston, MA: argenx US, Inc. **8.** RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. **9.** ULTOMIRIS [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc. **10.** NuFactor Specialty Pharmacy. IVIG brands. Accessed November 13, 2023. https://www.pemphigus.org/wp-content/uploads/IVIG-Brands.pdf. **11.** AmeriPharma Specialty Care. IVIG brands: in-depth guide. Accessed November 13, 2023. https://ameripharmaspecialty.com/ivig-brand-reviews/.

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