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 with anti-AChR Ab+ gMG ranging from MGFA Clinical Classification II to IV.[2]

Ab=antibody; AChR=acetylcholine receptor; FDA=US Food and Drug Administration; gMG=generalized myasthenia gravis; 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

ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. 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 ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.**
- **Patients receiving ZILBRYSQ 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, 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			
OR			
☐ MenABCWY			

Patients should complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) 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 meningococcal vaccines according to the full ZILBRYSQ Prescribing Information, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.[2]

4 Medication History[4-10]

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

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

AChE=acetylcholinesterase; FcRn=neonatal Fc receptor; IST=immunosuppressive therapy; IVIg=intravenous immunoglobulin; MenABCWY=meningococcal serogroups ABCWY; MenACWY=meningococcal serogroups ACWY; 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.
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)

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: _____

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

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

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. 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 ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.**
- **Patients receiving ZILBRYSQ 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, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

ZILBRYSQ, 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. The initiation of ZILBRYSQ treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.

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

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 serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor.

If urgent ZILBRYSQ 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.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Consider interruption of ZILBRYSQ in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

ZILBRYSQ REMS

Due to the risk of serious 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 serious 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

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported in patients treated with complement inhibitors. 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* infection according to ACIP recommendations. Patients receiving ZILBRYSQ are at increased risk for infections due to these organisms, even if they develop antibodies following 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. Available at: https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2025-Update/icd10cm-table-index-April-2025.zip. Accessed March 4, 2025. **2.** ZILBRYSQ [prescribing information]. Smyrna, GA: UCB, Inc. **3.** Centers for Disease Control and Prevention. Recommended adult immunization schedule for ages 19 years or older. Available at: https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf. Published November 11, 2024. Accessed March 4, 2025. **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. Intravenous immune globulin products. Available at: https://www.nufactor.com/products/ivig.html. Accessed March 6, 2025.

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