Oscar Clinical Guideline: Fleqsuvy (baclofen oral suspension) (PG112, Ver. 4)

Fleqsuvy (baclofen oral suspension)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Fleqsuvy (baclofen oral suspension) is a skeletal muscle relaxant indicated for the treatment of spasticity resulting from multiple sclerosis (MS) and spinal cord injuries/diseases. Fleqsuvy (baclofen oral suspension)is a gamma-aminobutyric acid (GABA-ergic) agonist, and while its exact mechanism of action is unknown, it is postulated to work by decreasing excitatory neurotransmitter release that may contribute to spasticity. It is also considered for certain off-label uses, such as alcohol use disorder (AUD) and intractable hiccups, in those who are unable to tolerate or use baclofen tablets. Fleqsuvy's concentrated liquid formulation (5 mg/mL) offers precise dosing and ease of administration, making it particularly beneficial for those with swallowing difficulties, those requiring enteral feeding, or those needing flexible dosing adjustments.

Definitions

"Alcohol Use Disorder (AUD)" is a medical condition characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences. Baclofen has been studied as a treatment option for reducing alcohol cravings and preventing relapse, particularly in patients with liver disease.

"Autoimmune Disease" is a condition in which the body's immune system mistakenly targets and attacks its own healthy cells and tissues.

"Central Nervous System (CNS)" is the part of the nervous system that includes the brain and spinal cord, responsible for receiving, processing, and transmitting information throughout the body.

"Enteral Feeding" is a method of delivering nutrition or medication directly into the stomach or small intestine via a feeding tube, often used for patients unable to swallow or take oral medications.

"Hiccups" are involuntary contractions of the diaphragm followed by rapid closure of the vocal cords, causing a characteristic "hic" sound. Chronic or intractable hiccups lasting more than 48 hours may require medical intervention, including off-label use of baclofen.

"Immune System" is the body's defense system that protects against infections and diseases by recognizing and attacking foreign substances, such as viruses, bacteria, or abnormal cells.

"Multiple Sclerosis (MS)" is an autoimmune disease in which the body's immune system mistakenly attacks the protective covering of nerve fibers (myelin) in the central nervous system, leading to communication problems between the brain and the rest of the body.

"Myelin" is a fatty substance that forms a protective sheath around nerve fibers, enabling efficient transmission of electrical signals between nerve cells.

"Spasticity" is a condition characterized by increased muscle tone and stiffness, leading to involuntary muscle contractions, muscle spasms, and difficulty with movement and coordination.

"Swallowing Difficulties (Dysphagia)" refers to a condition that impairs the ability to swallow, often necessitating the use of liquid formulations or enteral feeding for medication administration.

Medical Necessity Criteria for Initial Authorization

The Plan considers Fleqsuvy (baclofen oral suspension) medically necessary when ALL of the following criteria are met:

1. The member has ONE (1) of the following diagnoses:
    a. Spasticity associated with multiple sclerosis (MS)*; or*
    b. Spasticity associated with spinal cord injury or disease*; or*
    c. Off-label indications:
        i. Alcohol use disorder (AUD), particularly in members with liver disease*; or*
        ii. Intractable hiccups unresponsive to first-line therapies; *AND*
2. The member is unable to use, or has tried and failed, baclofen oral tablets due to one of the following
    a. Swallowing difficulties (e.g., dysphagia)*; or*
    b. Intolerance to tablets (e.g., gastrointestinal side effects, poor absorption)*; or*

c. Need for precise dosing adjustments or administration via feeding tube; *AND*

3. Fleqsuvy (baclofen oral suspension) will prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*
4. Documentation is provided to substantiate the above-listed requirements, including the diagnosis, inability to use tablets, and treatment plan.

<u>If the above prior authorization criteria are met, Fleqsuvy (baclofen oral suspension) will be approved for up to 12 months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if BOTH of the following are met:

1. The member still meets the applicable Initial Authorization criteria; *AND*
2. Chart documentation shows the member has experienced a clinical improvement in symptoms since starting the requested medication.

   Examples of clinical improvement include:

   - *For spasticity: reduction in muscle spasms, improved range of motion, or enhanced ability to perform activities of daily living.*
   - *For AUD: reduction in alcohol cravings, improved abstinence rates, or stabilization of liver function.*
   - *For intractable hiccups: resolution or significant reduction in hiccup frequency or severity.*

Experimental or Investigational / Not Medically Necessary

Fleqsuvy (baclofen oral suspension) for any other indication is considered not medically necessary by the Plan, as this is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Anxiety disorders.
- Lower urinary tract symptoms (LUTS).
- Muscle cramps.
- Nicotine dependence.
- Overactive bladder syndrome (OABS).
- Recurrent crying spells.
- Rumination disorders.

Appendix

Table 1: Dosage and Retreatment Information

Indication	Initial Dose	Titration	Maximum Dose	Monitoring Recommendations
Spasticity (FDA-approved)	5 mg (1 mL) 3 times daily	Increase by 5 mg (1 mL) per dose every 3 days based on response and tolerability	80 mg/day (20 mg [4 mL] 4 times daily)	Monitor for reduction in spasticity, muscle spasms, and improvement in functional abilities
Alcohol Use Disorder (AUD)	5 mg (1 mL) 3 times daily	Increase to 10 mg (2 mL) 3 times daily after 3–5 days; further increases as needed	60 mg/day (in divided doses)	Monitor liver function, alcohol cravings, and abstinence rates
Intractable Hiccups	5–10 mg (1–2 mL) 3 times daily	Increase based on response and tolerability	45 mg/day (in divided doses)	Monitor for resolution or reduction in hiccup frequency and severity
Other Off-Label Uses	Not covered	Not applicable	Not applicable	Not applicable

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Clinical Guideline Revision / History Information

Original Date: 06/23/2022 Reviewed/Revised: 06/29/2023, 12/19/2024, 01/01/2026