CountyCare
A MEDICAID HEALTH PLAN

Provider Notice

May 19, 2026

Montelukast (Singulair®) – Neuropsychiatric Safety Warning

The purpose of this notice is to inform providers of important safety updates regarding montelukast and the risk of serious neuropsychiatric adverse events. This notice also reinforces appropriate prescribing and monitoring practices.

Background
Montelukast (brand name: Singulair®) is a leukotriene receptor antagonist indicated for asthma (prophylaxis and chronic treatment), prevention of exercise-induced bronchoconstriction, and allergic rhinitis. In March 2020, the U.S. Food and Drug Administration issued a boxed warning due to the risk of serious neuropsychiatric adverse events associated with montelukast use.

Safety Concern
Serious neuropsychiatric adverse events have been reported in patients taking montelukast, including agitation, aggression, anxiety, depression, sleep disturbances (such as insomnia and nightmares), hallucinations, and suicidal thoughts or behavior, including completed suicide. These events have occurred during treatment and, in some cases, after discontinuation and have been reported in patients both with and without a prior history of psychiatric illness.

The U.S. Food and Drug Administration recommends the following:

- Avoid prescribing montelukast for patients with mild symptoms, particularly for allergic rhinitis, when alternative therapies are appropriate.
- Reserve use for patients who have an inadequate response or intolerance to alternative treatments.
- Discuss risks and benefits with patients and caregivers prior to initiation.
- Discontinue montelukast immediately if neuropsychiatric symptoms occur.
- Monitor all patients for behavioral or mood-related changes.

Clinical Considerations
Providers should carefully evaluate the overall risk-benefit profile when prescribing montelukast, particularly in patients with mild disease (such as allergic rhinitis) or a history of psychiatric illness. Alternative therapies should be considered when appropriate, including inhaled corticosteroids for asthma and intranasal corticosteroids or oral antihistamines for allergic rhinitis. Providers are encouraged to counsel patients and caregivers on the potential for neuropsychiatric side effects and to emphasize the importance of promptly reporting any changes in mood, behavior, or sleep patterns.

References

U.S. Food and Drug Administration Drug Safety Communication (March 2020)
Montelukast Prescribing Information

Thank you for working with us to ensure that CountyCare members receive quality care at the right time and in the right setting. If you have any questions or would like additional information, please contact CountyCare Provider Services at countycareproviderservices@cookcountyhhs.org or your assigned provider relations representative.