INTERNET NEWS

BS TRẦN TẤN HƯNG

FDA OKs Subcutaneous Lecanemab Maintenance Dosing for Early AD

Megan Brooks
September 02, 2025

0 18

Added to Email Alerts

The FDA has approved a subcutaneous formulation of lecanemab (Leqembi Iqlik, Eisai/Biogen) for maintenance dosing in patients with Alzheimer's disease (AD) with mild cognitive impairment (MCI) or mild dementia stage of disease.

After 18 months of lecanemab (Leqembi) intravenous (IV) treatment at 10 mg/kg every 2 weeks, patients may either continue IV infusions at 10 mg/kg once every 4 weeks or switch to the new weekly 360-mg subcutaneous injection using the Leqembi Iqlik autoinjector.

The data showed that transitioning to the weekly subcutaneous dosing after 18 months of IV dosing maintained clinical and biomarker benefits comparable to those obtained with continued IV dosing, the company said in a statement.

The safety profile of subcutaneous administration mirrored that of the IV maintenance treatment, although systemic reactions were less common with subcutaneous dosing (< 1% vs 26% with IV infusions).

Approximately 11% of patients using subcutaneous lecanemab experienced mild-to-moderate local reactions (redness, swelling, or itching at the injection site), which did not interfere with continued administration.

Rates of amyloid-related imaging abnormalities (ARIAs) in patients who received a weekly 360 mg subcutaneous maintenance dose were similar to ARIA rates reported in patients who continued with the IV dose after 18 months. Most ARIAs with lecanemab occur within the first 6 months of IV initiation treatment, the company noted.

Lecanemab subcutaneous autoinjector will be available in the US starting October 6, the company said.

Alzheimer's is not a "one-target disease, and the future lies in precision combination therapies tailored to each patient based on their individual biomarker profiles," Fillit noted.

"Subcutaneous delivery is more than an upgrade — it's a gateway to the next generation of Alzheimer's care, accelerating our ability to bring effective, multi-modal treatment regimens to the millions of patients who need them," he added.

https://www.medscape.com/viewarticle/fda-oks-subcutaneous-lecanemab-maintenance-dosing-early-ad-2025a1000n3r

Repeat Intubation of the Sigmoid Colon Improves Adenoma Detection

Nancy A. Melville
September 10, 2025

A colonoscopy technique involving repeat intubation of the sigmoid colon significantly improves detection of adenomas compared with conventional colonoscopy evaluations, new research showed.

"After eliminating the impact of time, the adenoma-detection rate [with a second intubation vs standard withdrawal] was still significantly increased, indicating that the second intubation technique could enhance the visualization of the sigmoid colon mucosa and reduce the rate of missed lesions," reported the authors in the study, published in *The American Journal of Gastroenterology*.

When precancerous polyps are removed during standard colonoscopies, as many as 70% to 90% of colorectal cancers can be prevented; however, rates of missed polyps during colonoscopy are notoriously high.

To investigate if use of a second colon intubation of the sigmoid colon could improve detection rates, senior author Jianning Yao, MD, of the Department of Gastroenterology, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China, conducted a randomized trial, enrolling 650 patients between December 2023 and April 2024 who were aged 45 or older and had overweight or obesity (BMI $\geq$ 24).

At the time of the first withdrawal during the colonoscopy, the patients were randomized 1:1 to groups of 325 each to either receive standard withdrawal, with withdrawal to the anus, or to receive a second intubation, with reinsertion into the sigmoid colon.

In the second intubation, the colonoscope was pushed forward without straightening, "allowing for slight looping that could be used to flatten the colonic folds as the tip of the instrument was advanced," they explained.

The patients had a mean age of 55; about 25% had a smoking habit, and the mean BMI was about 28. There were no significant differences in other baseline characteristics.

The results showed that patients in the second-intubation group vs standard-withdrawal group had substantially higher adenoma-detection rate (24.3% vs 14.5%) and polyp-detection rate (29.2% vs 17.8%, $P = .001$ for both) in the sigmoid colon.

In the second-intubation group, 85% of the adenomas discovered throughout the second inspection in the sigmoid colon were 5 mm or smaller in size. In addition, 90% of the 40 adenomas were somewhat raised or pedunculated, and all were tubular adenomas.

No high-grade dysplasia adenomas were discovered.

Of note, the colonoscopy in the second-intubation group's colonoscopic examinations took just 1.47 minute longer overall than the standard-withdrawal group's examinations.

Alternative to Axis-Keeping Shortening (AKS) Approach in Second Intubation Used

The authors explained that, in their approach in the second intubation, the common AKS was not utilized, and instead they pushed the colonoscope forward without straightening it, which offers important advantages.

“In this way, slight looping of the colonoscope can be used to flatten the colonic folds as the tip of the instrument is advanced, thereby achieving an observation effect that cannot be reached by any number of withdrawal examinations.”

In general, the stimulation of peristalsis during a second examination allows for the observation of the colonic mucosa from different angles, thereby reducing the rate of missed lesions, the authors added.

“Although the detection of these lesions may not significantly affect clinical outcomes, it serves as a reminder for patients regarding regular follow ups and lifestyle adjustments,” they explain. “Additionally, it may reduce the likelihood of missing some smaller lesions that progress rapidly, such as de novo cancer.”

Based on the results, the authors concluded that older patients, patients who smoke, or those with lesions found on the first sigmoid inspection have a higher chance of having missed adenomas discovered in the sigmoid colon during the second intubation examination.

https://www.medscape.com/viewarticle/repeat-intubation-sigmoid-colon-improves-adenoma-detection-2025a1000nxc

Eosinophilic Esophagitis Is More Common in Patients With Atopic Diseases

Edited by Mandeep Singh Rawat
September 05, 2025

METHODOLOGY:

- Researchers conducted a cross-sectional study to assess the prevalence and odds of EoE across patients with various atopic diseases and examine associated demographic characteristics and risk factors.
- They analyzed the data of 1,110,189 patients (89.6% men; 81.3% White individuals) sourced from the US Veterans Health Administration database from 2009 to 2021.
- The researchers collected patient data on atopic diseases such as asthma, eczema, allergic rhinitis, and food allergies.

TAKEAWAY:

- Overall, 26% (288,193) had at least one atopic disease, and 0.092% (1022) had an EoE diagnosis.
- Among patients with atopic diseases, those with milk allergy had the highest odds of developing EoE (odds ratio [OR], 49.43; 95% CI, 24.28-100.66), followed by those with egg allergy (OR, 11.65; 95% CI, 4.81-28.17) and wheat allergy (OR, 9.46; 95% CI, 5.21-17.18). By contrast, patients with asthma (OR, 3.12; 95% CI, 2.60-3.76) or rhinitis (OR, 3.09; 95% CI, 2.71-3.53) had lower odds.
- Men with allergies (OR, 2.87; 95% CI, 2.52-3.27) and women with allergies (OR, 3.29; 95% CI, 2.53-4.21) had higher odds of developing EoE than men without allergies.
- Milk allergy was the strongest predictor of EoE (adjusted OR, 19.9; 95% CI, 8.39-40.63).

IN PRACTICE:

"Providers should have a high clinical suspicion for EoE if a patient has GI [gastrointestinal] symptoms with history of atopic disease and especially milk, wheat, or egg allergy," the authors wrote. "Consideration should be given to screening all patients with atopic disease for upper GI symptoms, and early diagnosis of EoE is crucial to improved treatment outcomes," they added.

https://www.medscape.com/viewarticle/eosinophilic-esophagitis-more-common-patients-atopic-2025a1000nhh

Serum Ferritin Levels Serve as Biomarker of Disease Activity in Juvenile Idiopathic Arthritis

Edited by Vinod Rane, BS Pharm

UK

TOPLINE:

Children with systemic juvenile idiopathic arthritis (sJIA; Still disease) and those with rheumatoid factor (RF)-positive polyarthritis exhibiting high disease activity had higher serum ferritin levels than those with other JIA subtypes, underscoring serum ferritin's potential as a marker of disease activity across all JIA subtypes.

METHODOLOGY:

- Researchers conducted a retrospective study to evaluate the role of serum ferritin as a marker of disease activity within the full spectrum of JIA subtypes in children.
- They evaluated 139 children with JIA and categorised them as those with persistent oligoarthritis, extended oligoarthritis, RF-negative polyarthritis, RF-positive polyarthritis, enthesitis-related arthritis, psoriatic arthritis, or sJIA.
- Disease activity was assessed using the Juvenile Arthritis Disease Activity Score 10 (JADAS-10), with scores classifying the disease state as inactive disease, low disease activity, moderate disease activity, or high disease activity.

TAKEAWAY:

- Children with sJIA and RF-positive polyarthritis had significantly higher serum ferritin levels than those with other JIA subtypes (*P* < .0001 for both).
- The highest serum ferritin levels were observed in children with sJIA and RF-positive polyarthritis with high disease activity (*P* = .003).
- A positive association was observed between serum ferritin levels and JADAS-10 scores, independent of BMI and age (*P* < .0001), which remained significant in patients with sJIA (*P* < .0001) and RF-positive polyarthritis (*P* = .008).

IN PRACTICE:

"Serum ferritin might serve as a clinically and prognostically useful biomarker across the full spectrum of JIA subtypes, with particular relevance in sJIA and RF-positive polyarthritis," the authors wrote.

https://www.medscape.com/viewarticle/serum-ferritin-levels-serve-biomarker-disease-activity-2025a1000n1y

Reducing MMI Dose Pre-Stop Cuts Relapse in Graves Disease

Nancy A. Melville
September 15, 2025

SCOTTSDALE, AZ — In patients with Graves disease, prescribing a lower maintenance dose of methimazole (MMI) before discontinuing the drug is associated with significantly higher rates of remission, compared with a higher dose, according to a new study presented at the 2025 American Thyroid Association Annual Meeting.

“If further research confirms this association, these findings could contribute to revisions in clinical guidelines and encourage the broader adoption of tailored tapering strategies in clinical practice,” the researchers wrote in the study, which was published online in the *Journal of Clinical Endocrinology and Metabolism*. “These strategies could substantially reduce the number of relapsed cases, considering the global prevalence of Graves’ disease.”

Relapse of Graves disease after standard antithyroid treatment with MMI and other antithyroid drugs is common, ranging from 20% up to 70%, with risk factors including the total duration of time on antithyroid medication and the length of time patients remain on a minimum dose, the authors noted.

As Dose Decreases, Relapse Risks Falls

The researchers identified 4352 patients at Kuma Hospital who were newly diagnosed with Graves disease between 2008 and 2024 and who had discontinued MMI after receiving a minimal maintenance dose of 2.5 mg per day or less.

The patients were categorized into four groups according to their final maintenance dose prior to discontinuing MMI: 2.5 mg/day (n = 3523); > 1.25 to < 2.5 mg/day (n = 526); 1.25 mg/day (n = 227); and < 1.25 mg/day (n = 76). Those who had doses below 2.5 mg received the pill every other day.

The rates of relapse at 1 year in the four groups were 13.8% for a maintenance dose of 2.5 mg/day; 13.1% with > 1.25 to < 2.5 mg/day; 7.1% with 1.25 mg/day; and 2.6% in the < 1.25 mg group.

Of note, 85.5% of those in the 1.25 mg/day group had thyrotropin receptor antibody (TRAb) titers below the detection limit at baseline, compared with approximately 55% in the < 1.25 and > 1.25 to < 2.5 mg/day groups and 45.8% in the 2.5 mg/day group.

After adjusting for factors — including age, sex, thyroid volume, smoking status, total duration of MMI treatment, duration of maintenance dose, and TRAb titer at the time of discontinuation — the associations were unchanged.

Compared with those tapered at 2.5 mg/day, the adjusted risk ratios (RRs) for relapse were 0.92 for the > 1.25 to < 2.5 mg/day group, 0.46 for the 1.25 mg/day group, and 0.18 for the < 1.25 mg/day group.

"A statistically significant trend was observed across dose categories (*P* for trend <.05), suggesting a dose-response relationship where lower MMI doses prior to discontinuation were associated with a reduced risk of relapse," the authors reported.

Clinical Implications

While TRAb negativity can guide discontinuation, relapse rates can still vary, and — particularly in older populations — longer-duration low-dose MMI can be beneficial, James Hennessey, MD, an associate professor of medicine, at Beth Israel Deaconess Medical Center in Boston, told *Medscape Medical News*.

“I've got a lot of patients, especially older patients, who have been reduced to 1.25 mg per day or 2.5 mg per day, and others might say ‘that's such a small dose, what good is it doing?’ But when they discontinue, the hyperthyroidism comes back,” added Hennessey, who was not involved in the study. “So, a lot of people get by on very low doses, and it can be just enough to keep them in balance and keep their thyroid function normal.”

Akamizu said that he continues patients on the low dose, even if their TRAb levels are negative.

“Patients are generally more satisfied with the 1.25 dose, probably because they feel [they are] getting better or approaching the remission,” he added.

The study findings show that “dose reduction is feasible in daily practice,” Akamizu said.

“The take-home message from this for clinicians should be to try the lower dose of MMI if your aim is the remission of Grave’ disease,” he said.

Akamizu and Hennessey had no disclosures to report related to the study.

https://www.medscape.com/viewarticle/reducing-mmi-dose-pre-stop-cuts-relapse-graves-disease-2025a1000ocw

Johns Hopkins researchers develop urine-based prostate cancer test

The test, supported partly by funding from the National Institutes of Health, leverages biomarkers found in urine to detect the disease.

September 15, 2025

Researchers from Johns Hopkins Kimmel Cancer Centre, Johns Hopkins All Children's Hospital, and other institutions have developed a new urine-based test to identify prostate cancer, potentially reducing the reliance on invasive biopsies.

The test utilises biomarkers found in urine to detect the disease and was partially supported by funding from the US National Institutes of Health.

The study analysed urine samples from both prostate cancer patients and healthy individuals, identifying three key biomarkers, namely TTC3, H4C5, and EPCAM, that were effective in detecting prostate cancer.

The biomarkers, present before prostate-removal surgery but nearly absent post-surgery, were confirmed to originate in prostate tissue.

Senior study author Ranjan Perera said: "This new biomarker panel offers a promising, sensitive, and specific, noninvasive diagnostic test for prostate cancer.

"It has the potential to accurately detect prostate cancer, reduce unnecessary biopsies, improve diagnostic accuracy in PSA-negative patients, and serve as the foundation for both laboratory-developed and in vitro diagnostic assays."

Currently, prostate cancer is often detected through blood tests measuring prostate-specific antigen (PSA) levels, which can lead to biopsies if results are abnormal.

Many biopsies prove negative and can cause complications while PSA tests may also result in unnecessary treatment for low-grade cancers.

The new biomarker panel is said to detect prostate cancer even when PSA levels are normal and can differentiate between cancer and conditions like prostatitis and benign prostatic hyperplasia.

Study co-author Vipul Patel said: “This test has the potential to help physicians improve diagnostic accuracy of prostate cancer, reducing unnecessary interventions while allowing early treatment for those who need it.

“On behalf of physicians and patients globally, I advocate for further study and progress for these biomarkers.”

Researchers examined 341 initial urine samples and an additional 1,055 for test validation.

They used techniques such as RNA sequencing and qPCR to analyse gene expression and confirmed the findings with immunohistochemistry and statistical analysis.

From the 815 prostate-specific genes initially identified, researchers narrowed down to the three top-performing biomarkers for further analysis.

The biomarkers showed higher expression in cancer patients compared to healthy individuals and diminished after surgery.

Future steps include independent trials and developing the test for clinical use. A patent has been filed, and efforts are underway to commercialise the technology with assistance from Johns Hopkins Technology Ventures.

The research received support from various organisations, including the International Prostate Cancer Foundation and the Maryland Innovation Initiative Grant.

Study co-author Christian Pavlovich said: "There is a real need for non-PSA-based biomarkers for prostate cancer, and urine is quite easy to collect in the clinic.

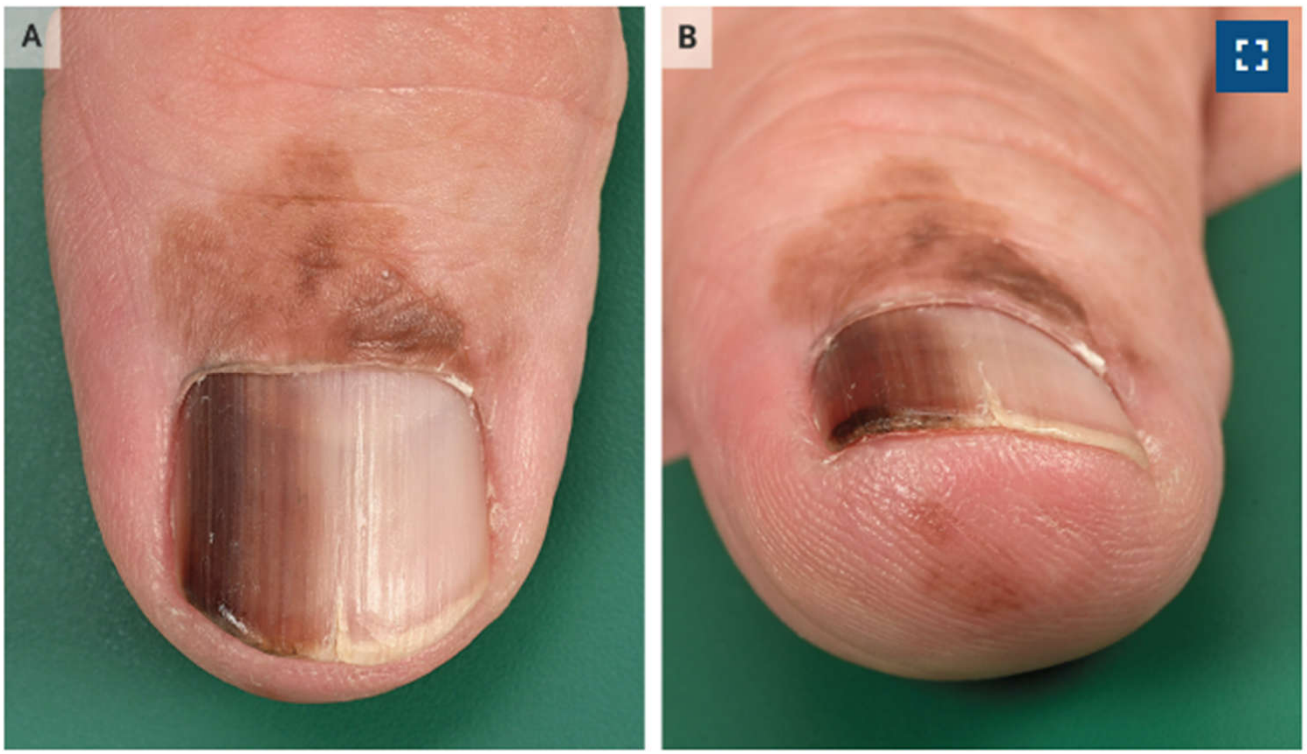
"Most urologists feel that an accurate urinary biomarker would be a valuable addition to our current diagnostic armamentarium."

https://www.medicaldevice-network.com/news/johns-hopkins-prostate-cancer/?utm_source=chatgpt.com&cf-view&cf-closed

Hutchinson's Sign in Subungual Melanoma In Situ

Authors: Marcel Pasch, M.D., Ph.D., and Julie Tutein Nolthenius, M.D. Author Info & Affiliations

Published September 3, 2025 | N Engl J Med 2025;393: e13 | DOI: 10.1056/NEJMicm2504151 | VOL. 393 NO. 9



A 71-year-old man presented to the dermatology clinic with a 2-year history of a gradually darkening line on his left thumbnail. He had not sought evaluation previously because he had hoped the nail changes would resolve on their own. Physical examination was notable for an 8-mm-wide brown discoloration along the ulnar aspect of the left thumbnail and an irregularly shaped, sharply demarcated patch of hyperpigmentation on the proximal nail fold (Panel A). Hyperpigmented macules were also observed on the tip of the thumb (Panel B). The darkening of the skin around the hyperpigmented fingernail was consistent with Hutchinson's sign — a finding that arouses concern for subungual melanoma but may be seen in benign conditions. When Hutchinson's sign is present, a biopsy of the nail matrix — not the periungual hyperpigmentation — is warranted to evaluate for melanoma. In this case, a tangential excision of the hyperpigmented area of the nail matrix revealed melanocytes with limited atypia and enlarged, polymorphic nuclei in the epidermis without invasion of the dermis. A diagnosis of subungual melanoma in situ was made. A multidisciplinary melanoma treatment committee recommended wide local excision, but the patient opted for amputation of the distal tip of the thumb. At a 6-month follow-up visit, the patient had recovered well and had no recurrence.

https://www.nejm.org/doi/full/10.1056/NEJMicm2504151

Aficamten or Metoprolol Monotherapy for Obstructive Hypertrophic Cardiomyopathy

Authors: Pablo Garcia-Pavia, M.D., Ph.D., Martin S. Maron, M.D., Ahmad Masri, M.D., Bela Merkely, M.D., Michael E. Nassif, M.D., Maria Luisa Peña-Peña, M.D., Roberto Barriales-Villa, M.D., Ph.D., +26 , for the MAPLE-HCM Investigators* Author Info & Affiliations

BACKGROUND

Beta-blockers have been the initial treatment for symptomatic obstructive hypertrophic cardiomyopathy (HCM) despite limited evidence of their efficacy. Aficamten is a cardiac myosin inhibitor that reduces left ventricular outflow tract gradients, improves exercise capacity, and decreases HCM symptoms when added to standard medications. Whether aficamten as monotherapy provides greater clinical benefit than beta-blockers as

METHODS

We conducted an international, double-blind, double-dummy trial in which adults with symptomatic obstructive HCM were randomly assigned in a 1:1 ratio to receive aficamten (at a daily dose of 5 mg to 20 mg) plus placebo or metoprolol (at a daily dose of 50 mg to 200 mg) plus placebo. The primary end point was the change in peak oxygen uptake at week 24; secondary end points were improvement at week 24 in New York Heart Association (NYHA) functional class and changes at week 24 in Kansas City Cardiomyopathy Questionnaire clinical summary score (KCCQ-CSS), left ventricular outflow tract gradient after the Valsalva maneuver, N-terminal pro–B-type natriuretic peptide (NT-proBNP) level, left atrial volume index, and left ventricular mass index.

RESULTS

Aficamten or Metoprolol for Obstructive Hypertrophic Cardiomyopathy

A total of 88 patients were assigned to the aficamten group and 87 to the metoprolol group. The mean age of the patients was 58 years, 58.3% were men, and the mean left ventricular outflow tract gradient was 47 mm Hg at rest and 74 mm Hg after the Valsalva maneuver. At 24 weeks, the change in the peak oxygen uptake was 1.1 ml per kilogram of body weight per minute (95% confidence interval [CI], 0.5 to 1.7) in the aficamten group and −1.2 ml per kilogram per minute (95% CI, −1.7 to −0.8) in the metoprolol group (least-squares mean between-group difference, 2.3 ml per kilogram per minute; 95% CI, 1.5 to 3.1; $P<0.001$). Patients who received aficamten had significantly greater improvements in NYHA class, KCCQ-CSS, left ventricular outflow tract gradient, NT-proBNP level, and left atrial volume index than patients who received metoprolol. No significant difference in left ventricular mass index was observed. Adverse events appeared to be similar in the two treatment groups.

CONCLUSIONS

Among patients with symptomatic obstructive HCM, aficamten monotherapy was superior to metoprolol monotherapy in improving peak oxygen uptake and hemodynamics and decreasing symptoms. (Funded by Cytokinetics; MAPLE-HCM ClinicalTrials.gov number, NCT05767346.)

https://www.nejm.org/doi/full/10.1056/NEJMoa2504654